UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC., *et.al.*, *Plaintiffs*, –v– NORRIS COCHRAN, *et al.*, *Defendants*.	Civil Action No. 3:21-cv-00806-FLW-LHG

DECLARATION OF JAMES W. BOYAN III IN SUPPORT OF AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CHILDREN'S HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS' MOTION TO INTERVENE

I, James W. Boyan III, declare and state as follows:

1. I am a partner at the law firm of Pasham Stein Walder Hayden, P.C., counsel to American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, The Children's Hospital Association, and American Society of Health-System Pharmacist ("Proposed Intervenors") in the above-captioned mater.

2. I submit this declaration in support of the Proposed Intervenors' Motion to Intervene. I make this declaration based upon my personal knowledge and, where appropriate, a review of the relevant case files. The facts set forth herein are true and correct to the best of my knowledge and belief.

3. Attached hereto as **Exhibit A** is a true and correct copy of the Declaration of Maureen Testoni in Support of Proposed Intervenors' Motion to Intervene, dated February 24, 2021 in the above-captioned matter.

4. Attached hereto as **Exhibit B** is a true and correct copy of the Intervenors' [Proposed] Answer in Intervention to Plaintiff's First Amended Complaint.

5. Attached hereto as **Exhibit C** is a true and correct copy of a Letter from Anat Hakim, General Counsel, Eli Lilly and Co. to Eric Hargan, Deputy Secretary, HHS, dated July 17, 2020, which is Exhibit E to the First Amended Complaint in *Eli Lilly & Co. v. Cochran*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. Jan. 25, 2021), ECF No. 17-6.

6. Attached hereto as **Exhibit D** is a true and correct copy of a Letter from Krista AM. Pedley, Assistant Surgeon General, Office of Pharm. Affairs, HHS to Derek L. Asay, Senior Director, Lilly USA, LLC, dated June 11, 2020, which is Exhibit E to the First Amended Complaint in *Eli Lilly & Co. v. Cochran*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. Jan. 25, 2021), ECF No. 17-4.

7. Attached hereto as **Exhibit E** is a true and correct copy of an Eli Lilly & Co. Notice, which is Exhibit G to the First Amended Complaint in *Eli Lilly & Co. v. Cochran*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. Jan. 25, 2021), ECF No. 17-8.

8. Attached hereto as **Exhibit F** is a true and correct copy of a Letter from Odalys Caprisecca, Executive Director, AstraZeneca to 340B Partners, dated August 17, 2020, which is Exhibit A to the Amended Complaint in *AstraZeneca Pharms. L.P. v. Cochran*, No. 1:21-cv-00027-LPS (D. Del. Feb. 12, 2021), ECF No. 13-1.

9. Attached hereto as **Exhibit G** is a true and correct copy of Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program, dated December 30, 2020.

10. Attached hereto as **Exhibit H** is a true and correct copy of a Letter from Robert P. Charrow, General Counsel, HHS to Anat Hakim, General Counsel, Eli Lilly and Co., dated

September 21, 2020, which is Exhibit K to the First Amended Complaint in *Eli Lilly & Co. v. Cochran*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. Jan. 25, 2021), ECF No. 17-12.

11. Attached hereto as **Exhibit I** is a true and correct copy of a Letter from Krista M. Pedley, Assistant Surgeon General, Office of Pharm. Affairs, HHS to Maureen Testoni, President & CEO, 340B Health, dated December 9, 2020, which is Exhibit L to the First Amended Complaint in *Eli Lilly & Co. v. Cochran*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. Jan. 25, 2021), ECF No. 17-13.

12. Attached hereto as **Exhibit J** is a true and correct copy of a Novo Nordisk Notice, dated December 1, 2020, an electronic version of which is available at https://www.340bhealth.org/files/Novo_Nordisk_12-1-2020.pdf.

13. Attached hereto as **Exhibit K** is a true and correct copy of a Sanofi Notice, dated July 2020, an electronic version of which is available at https://www.340bhealth.org/files/Sanofi_Notice_10_1_20.pdf.

14. Attached hereto as **Exhibit L** is a true and correct copy of Novartis Statement, dated October 30, 2020, an electronic version of which is available at https://www.novartis.us/news/statements/new-policy-related-340b-program.

15. Attached hereto as **Exhibit M** is a true and correct copy of a Memorandum from Kevin Gray, SVP, United Therapeutics Corp. to 340B Covered Entities, dated November 18, 2020, an electronic version of which is available at https://www.dropbox.com/s/swyrookjcwqxe58/United%20Therapeutics%20Letter%2011.20.2020%20%281%29.pdf?dl=0.

16. Attached hereto as **Exhibit N** is a true and correct copy of a Letter from 340B Coalition to Alex M. Azar, Secretary, HHS, dated July 16, 2020, an electronic version of which is

available at https://nysarh.org/wp-content/uploads/2020/08/340B-Coalition-Letter-Final-7.16.20.pdf.

17. Attached hereto as **Exhibit O** is a true and correct copy of a Letter from Thomas P. Nickels, EVP, AHA to Alex M. Azar, Secretary, HHS, dated July 30, 2020, an electronic version of which is available at https://www.aha.org/system/files/media/file/2020/07/aha-urges-hhs-take-action-against-drug-manufacturers-for-limiting-distribution-340b-drugs-letter-7-30-2020.pdf.

18. Attached hereto as **Exhibit P** is a true and correct copy of a Letter from Bruce Siegel, President & CEO, AEH to Alex Azar, Secretary, HHS, dated August 28, 2020, an electronic version of which is available at https://essentialhospitals.org/wp-content/uploads/2020/08/AEH-Letter-340B-Contract-Pharmacy-8-28-20.pdf.

19. Attached hereto as **Exhibit Q** is a true and correct copy of a Letter from Richard J. Pollack, President & CEO, AHA to Alex M. Azar, Secretary, HHS, dated September 8, 2020, an electronic version of which is available at https://www.aha.org/system/files/media/file/2020/09/aha-again-urges-hhs-to-protect-340b-program-from-drug-companies-actions-letter-9-8-20.pdf.

20. Attached hereto as **Exhibit R** is a true and correct copy of a Letter from Richard J. Pollack, President & CEO, AHA to Alex M. azar, Secretary, HHS, dated October 16, 2020, an electronic version of which is available at https://www.aha.org/system/files/media/file/2020/10/aha-urges-hhs-stop-drug-companies-refusal-provide-required-340b-discounts-letter-10-16-20.pdf

21. Attached as **Exhibit S** is a true and correct copy of a Pink Sheet article by Cathy Kelly titled *340B Dispute Resolution Process On Ice As Feuds Between Pharm, Providers, HHS Heat Up*, an electronic version of which is available at https://pink.pharmaintelligence.informa.com/PS143652/340B-Dispute-Resolution-Process-On-Ice-As-Feuds-Between-Pharma-Providers-HHS-Heat-Up.

Dated: March 2, 2021

/s/ James W. Boyan III
James W. Boyan III

EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC, *Plaintiff,* –v– NORRIS COCHRAN, *et al.*, *Defendants.*	Civil Action No. 3:21-cv-806

DECLARATION OF MAUREEN TESTONI IN SUPPORT OF THE AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS, THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES, THE CHILDREN'S HOSPITAL ASSOCIATION, AND THE AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACIST'S MOTION TO INTERVENE

I, Maureen Testoni, state as follows under the penalty of perjury:

1. I am the President and Chief Executive Officer of 340B Health, a national, not-for-profit organization headquartered in Washington, D.C. Our vision and mission is to be the leading 340B advocate and resource in helping hospitals serve their patients, so that 340B hospitals and health systems fulfill their mission to provide care for patients with low income and those living in rural communities.

2. The information set forth in this affidavit is based upon my personal knowledge.

3. Following Eli Lilly's June 2020 announcement that it would cease offering Cialis® at 340B pricing to 340B entities if dispensed by a contract pharmacy, 340B Health conducted a "Contract Pharmacy Survey." The survey was administered to all 340B Health hospital members (about 1500). Responses were received between July 14 and August 8, 2020. 435 hospitals responded. The respondent mix was 64% disproportionate share hospitals (DSH) hospitals, 24%

critical access hospitals (CAH), and 12% other hospital types. Data were cleaned to remove duplicates.

4. A second survey, the 340B Health Annual Survey, was launched on November 3, 2020. Responses were received between November 3, 2020 and January 7, 2021. 489 hospitals responded. The respondent mix included 61% DSH hospitals, 28% CAH hospitals, and 11% other hospital types. Data were cleaned to remove duplicates.

5. The following information is derived from those two 340B Health surveys.

6. Respondents to the Annual Survey reported that discounts for drugs dispensed through a contract pharmacy provided over half of the total 340B benefit from the 340B discounts for CAHs (51%) and about a quarter of the total such benefit for all 340B hospital types (27%).

7. Respondents to the Contract Pharmacy Survey reported that the reduction or elimination of the discounts for drugs dispensed through contract pharmacies would lead to cuts in programs and services for people with low income and/or living in rural areas.

8. Respondents to the Contract Pharmacy Survey reported using the discount benefit from 340B drugs dispensed through contract pharmacies to support programs and services offered by 340B hospitals. For example, respondents reported that the discount benefit from 340B drugs dispensed through contract pharmacies allows them to:

- Maintain/provide more patient care services (97%)
- Maintain/provide more uncompensated and unreimbursed care (93%)
- Maintain/provide more services in underserved areas (83%)
- Develop/maintain targeted programs to serve vulnerable patients (73%)
- Keep the doors open (70%)

9. Respondents to the Contract Pharmacy Survey reported that a reduction or elimination of discounts for drugs dispensed through a contract pharmacy would harm the ability

of 340B hospitals to maintain programs and services. Specific services that would be harmed include:

- Patient care services (94%)
- Uncompensated and unreimbursed care (86%)
- Services in underserved areas (81%)
- Programs to serve vulnerable patients (73%)

10. Sixty percent of respondents to the Contract Pharmacy Survey reported that a reduction in the discounts from 340B drugs dispensed through contract pharmacies could lead the hospital to close.

On this 26th day of February, 2021, I declare under penalty of perjury that the foregoing is true and correct.

Maureen Testoni
President and
Chief Executive Officer
340B Health

EXHIBIT B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC, *Plaintiff*, –v– NORRIS COCHRAN, *et al.*, *Defendants*.	Civil Action No. 3:21-cv-634-FLW-LHG

[PROPOSED] ANSWER IN INTERVENTION TO PLAINTIFF'S FIRST AMENDED COMPLAINT

Intervenors American Hospital Association, 340B Health, Association of American Medical Colleges, America's Essential Hospitals, National Association of Children's Hospitals d/b/a Children's Hospital Association, and American Society of Health-System Pharmacists (collectively the Intervenors) hereby answer the First Amended Complaint filed by Plaintiff Sanofi-Aventis U.S., LLC ("Plaintiff") as follows.

INTRODUCTION

1. The allegations in Paragraph 1 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

2. The allegations in Paragraph 2 address legal rather than factual matters and characterize section 340B of the Public Health Service Act, 42 U.S.C. § 256b, which is the best evidence of its content. To the extent that Paragraph 2 makes any material allegations that are inconsistent with the statute, they are denied.

3. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 3.

4. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 4.

5. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 5 and therefore deny the same.

6. The allegations in Paragraph 6 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

7. The allegations in Paragraph 7 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may deemed applicable, the allegations in Paragraph 7 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content. To the extent that Paragraph 7 makes any material allegations that are inconsistent with the Rule, they are denied.

8. The allegations in Paragraph 8 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

9. The allegations in Paragraph 9 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

10. The allegations in Paragraph 10 addresses legal rather than factual matters and characterize the Advisory Opinion issued on December 30, 2020, which is the best evidence of its content. To the extent that Paragraph 10 makes any material allegations that are inconsistent with the Advisory Opinion, they are denied.

11. The allegations in Paragraph 11 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

12. The allegations in Paragraph 12 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

13. The allegations in Paragraph 13 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

JURISDICTION AND VENUE

14. The allegations in Paragraph 14 are conclusions of law to which no response is required.

15. The allegations in Paragraph 15 are conclusions of law to which no response is required.

16. The allegations in Paragraph 16 are conclusions of law to which no response is required.

PARTIES

17. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 17 and therefore deny the same.

18. Intervenors admit the allegations contained in Paragraph 18.

19. Intervenors admit the allegations contained in Paragraph 19.

20. Intervenors admit the allegations contained in Paragraph 20.

21. Intervenors admit the allegations contained in Paragraph 21.

22. Intervenors admit the allegations contained in Paragraph 22.

STATEMENT OF FACTS

23. The allegations in Paragraph 23 addresses legal rather than factual matters and characterize the Advisory Opinion issued on December 30, 2020, which is the best evidence of its content.

24. The allegations in Paragraph 24 address legal rather than factual matters and characterize 42 U.S.C. § 256b, which is the best evidence of its content. To the extent that Paragraph 24 makes any material allegations that are inconsistent with the statute, they are denied.

25. The allegations in Paragraph 25 address legal rather than factual matters and characterize 42 U.S.C. § 256b, which is the best evidence of its content. To the extent that Paragraph 25 makes any material allegations that are inconsistent with the statute, they are denied.

26. The allegations in Paragraph 26 address legal rather than factual matters and characterize 42 U.S.C. § 256b, which is the best evidence of its content. To the extent that Paragraph 26 makes any material allegations that are inconsistent with the statute, they are denied.

27. The allegations in Paragraph 27 address legal rather than factual matters and characterize 42 U.S.C. § 256b, which is the best evidence of its content. To the extent that Paragraph 27 makes any material allegations that are inconsistent with the statute, they are denied.

28. The allegations in Paragraph 28 address legal rather than factual matters and characterize 42 U.S.C. § 256b, which is the best evidence of its content. To the extent that Paragraph 28 makes any material allegations that are inconsistent with the statute, they are denied.

29. The allegations in Paragraph 29 address legal rather than factual matters and characterize 42 U.S.C. § 256b, which is the best evidence of its content. To the extent that Paragraph 29 makes any material allegations that are inconsistent with the statute, they are denied.

30. The allegations in Paragraph 30 address legal rather than factual matters and characterize 42 U.S.C. § 256b, which is the best evidence of its content. To the extent that Paragraph 30 makes any material allegations that are inconsistent with the statute, they are denied.

31. The allegations in Paragraph 31 address legal rather than factual matters and characterize 42 U.S.C. § 256b, which is the best evidence of its content. To the extent that Paragraph 31 makes any material allegations that are inconsistent with the statute, they are denied.

32. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 32.

33. The allegations in Paragraph 33 address legal rather than factual matters and characterize the HRSA guidelines issued in 1996 which are the best evidence of its content. To the extent that Paragraph 33 makes any material allegations that are inconsistent with the HRSA guidelines, they are denied.

34. The allegations in Paragraph 34 address legal rather than factual matters and characterize the HRSA guidelines issued in 2010 which are the best evidence of its content. To the extent that Paragraph 34 makes any material allegations that are inconsistent with the HRSA guidelines, they are denied.

35. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 35.

36. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 36.

37. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 37.

38. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 38.

39. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 39.

40. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 40.

41. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 41 to the extent that they are not quoting from Exhibits 1, 2, 3, 4, or 5 and therefore deny the same.

42. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 42 to the extent that they are not quoting from Exhibits 6 or 7 and therefore deny the same.

43. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 43 and therefore deny the same.

44. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 44 and therefore deny the same.

45. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 45 and therefore deny the same.

46. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 46 and therefore deny the same.

47. Intervenors admit the allegations of Paragraph 47, except that Intervenors lack knowledge or information sufficient to form a belief about why the manufacturers implemented the policies referred to and therefore those allegations are denied. Intervenors also note that

Sanofi's motion to intervene in Am. Hosp. Ass'n v. HHS is no longer pending because the case has been dismissed.

48. The allegations in Paragraph 48 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations in Paragraph 48 address legal rather than factual matters and characterize the Affordable Care Act which is the best evidence of its content. To the extent that Paragraph 48 makes any material allegations that are inconsistent with the statute, they are denied.

49. The allegations in Paragraph 49 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations in Paragraph 49 address legal rather than factual matters and characterize the Affordable Care Act which is the best evidence of its content. To the extent that Paragraph 49 makes any material allegations that are inconsistent with the statute, they are denied.

50. The allegations in Paragraph 50 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations characterize the NPRM which is the best evidence of its content. To the extent that Paragraph 50 makes any material allegations that are inconsistent with the NPRM, they are denied.

51. The allegations in Paragraph 51 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the Intervenors admit the allegations in Paragraph 51, except for the statement that "HRSA took no public action regarding the ADR for more than four years," which is denied as incorrect.

52. The allegations in Paragraph 52 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the Intervenors

admit the allegations in Paragraph 52, except to note that there were only two lawsuits filed that sought to require HHS to issue the ADR regulations.

53. The allegations in Paragraph 53 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the Intervenors admit the allegations in Paragraph 53.

54. The allegations in Paragraph 54 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the Intervenors admit that HRSA published a final ADR rule on December 14, 2020 but lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 54 and therefore deny the same.

55. The allegations in Paragraph 55 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may deemed applicable, the allegations in Paragraph 55 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content. To the extent that Paragraph 55 makes any material allegations that are inconsistent with the Rule, they are denied.

56. The allegations in Paragraph 56 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the Intervenors lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny the same.

57. The allegations in Paragraph 57 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may deemed applicable, the allegations in Paragraph 57 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content.

58. The allegations in Paragraph 58 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may deemed applicable, the allegations in Paragraph 58 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content. To the extent that Paragraph 58 makes any material allegations that are inconsistent with the Rule, they are denied.

59. The allegations in Paragraph 59 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may deemed applicable, the allegations in Paragraph 59 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content. To the extent that Paragraph 59 makes any material allegations that are inconsistent with the Rule, they are denied.

60. The allegations in Paragraph 60 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may deemed applicable, the allegations in Paragraph 60 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content. To the extent that Paragraph 60 makes any material allegations that are inconsistent with the Rule, they are denied.

61. The allegations in Paragraph 61 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may deemed applicable, the allegations in Paragraph 61 address legal rather than factual matters and characterize the ADR Rule published by HRSA, which is the best evidence of its content. To the extent that Paragraph 61 makes any material allegations that are inconsistent with the Rule, they are denied.

62. The allegations in Paragraph 62 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

63. The allegation in Paragraph 63 addresses legal rather than factual matters and characterizes the Advisory Opinion issued on December 30, 2020, which is the best evidence of its content. To the extent that Paragraph 63 makes any material allegations that are inconsistent with the Advisory Opinion, they are denied.

64. The allegation in Paragraph 64 addresses legal rather than factual matters and characterizes the Advisory Opinion issued on December 30, 2020, which is the best evidence of its content. To the extent that Paragraph 64 makes any material allegations that are inconsistent with the Advisory Opinion, they are denied.

65. The allegation in Paragraph 65 addresses legal rather than factual matters and characterizes the Advisory Opinion issued on December 30, 2020, which is the best evidence of its content. To the extent that Paragraph 65 makes any material allegations that are inconsistent with the Advisory Opinion, they are denied.

66. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 66 to the extent that they are not quoting from Exhibits 13 or 14 and therefore deny the same.

67. Intervenors lack knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 67 to the extent that they are not accurately represented Exhibits 15 or 16 and therefore deny the same.

68. The allegations in Paragraph 68 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the Intervenors lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny the same.

STANDING

69. The allegations in Paragraph 69 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

70. The allegations in Paragraph 70 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations in Paragraph 70 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

71. The allegations in Paragraph 71 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations in Paragraph 71 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

72. The allegations in Paragraph 72 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations in Paragraph 72 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

73. The allegations in Paragraph 73 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

74. The allegations in Paragraph 74 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

75. The allegations in Paragraph 75 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

76. The allegations in Paragraph 76 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

77. The allegations in Paragraph 77 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations in Paragraph 77 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

78. The allegations in Paragraph 78 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations in Paragraph 78 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

79. The allegations in Paragraph 79 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

80. The allegations in Paragraph 80 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

81. The allegations in Paragraph 81 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

82. Intervenors deny the incomplete, out of context and misleading allegations contained in Paragraph 82.

CLAIMS FOR RELIEF

Count I—Violation of Administrative Procedure Act
The ADR Rule Violates Article II of the U.S. Constitution (Appointments Clause)

83. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–82.

84. The allegations in Paragraph 84 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations in

Paragraph 84 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content.

85. The allegations in Paragraph 85 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations address legal rather than factual matters and characterize the Appointments Clause of the U.S. Constitution, which is the best evidence of its content.

86. The allegations in Paragraph 86 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

87. The allegations in Paragraph 87 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

88. The allegations in Paragraph 88 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

89. The allegations in Paragraph 89 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

Count II—Violation of Administrative Procedure Act
The ADR Rule Violates Article III of the Constitution

90. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–89.

91. The allegations in Paragraph 91 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations in Paragraph 91 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content and to which no response is required.

92. The allegations in Paragraph 92 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may deemed applicable, the allegations address legal rather than factual matters and characterize Article III of the U.S. Constitution which is the best evidence of its content and to which no response is required.

93. The allegations in Paragraph 93 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

94. The allegations in Paragraph 94 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

Count III—Violation of Administrative Procedure Act
The ADR Rule Is Contrary to Law and in Excess of Statutory Authority

95. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–94.

96. The allegations in Paragraph 96 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations in Paragraph 96 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content and to which no response is required.

97. The allegations in Paragraph 97 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

98. The allegations in Paragraph 98 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

99. The allegations in Paragraph 99 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

100. The allegations in Paragraph 100 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

101. The allegations in Paragraph 101 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

Count IV—Violation of Administrative Procedure Act
HHS Failed to Observe the Notice-and-Comment Procedure Required by Law in Promulgating the ADR Rule

102. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–101.

103. The allegations in Paragraph 103 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations

in Paragraph 103 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content, and no response is required.

104. The allegations in Paragraph 104 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations in Paragraph 104 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content and to which no response is required.

105. The allegations in Paragraph 105 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations in Paragraph 105 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content and to which no response is required.

106. The allegations in Paragraph 106 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

107. The allegations in Paragraph 107 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

108. The allegations in Paragraph 108 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

109. The allegations in Paragraph 109 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

Count V—Violation of Administrative Procedure Act
The ADR Rule Is Arbitrary and Capricious

110. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–109.

111. The allegations in Paragraph 111 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations in Paragraph 111 address legal rather than factual matters and characterize the Administrative Procedure Act, which is the best evidence of its content, to which no response is required.

112. The allegations in Paragraph 112 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

113. The allegations in Paragraph 113 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

114. The allegations in Paragraph 114 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

115. The allegations in Paragraph 115 are not applicable to Plaintiff's allegations that are the basis for Intervenors' motion. To the extent they may be deemed applicable, the allegations are conclusions of law to which no response is required.

Count VI—Violation of Administrative Procedure Act
HHS Failed to Observe the Notice-and-Comment Procedure Required by Law in Promulgating the Advisory Opinion

116. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–115.

117. The allegations in Paragraph 117 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

118. The allegations in Paragraph 118 addresses legal rather than factual matters and characterize the Advisory Opinion issued on December 30, 2020, which is the best evidence of its content. To the extent that Paragraph 118 makes any material allegations that are inconsistent with the Advisory Opinion, they are denied.

119. The allegations in Paragraph 119 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

120. The allegations in Paragraph 120 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

121. The allegations in Paragraph 121 are conclusions of law to which no response is required.

Count VII—Violation of Administrative Procedure Act
HHS Failed to Follow Its Good Guidance Rule

122. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–122.

123. The allegations in Paragraph 123 address legal rather than factual matters and characterize the Administrative Procedure Act which is the best evidence of its content and to which no response is required.

124. The allegations in Paragraph 124 address legal rather than factual matters and characterize the Good Guidance Rule which is the best evidence of its content and to which no response is required.

125. The allegations in Paragraph 125 address legal rather than factual matters and characterize the Good Guidance Rule which is the best evidence of its content and to which no response is required.

126. The allegations in Paragraph 126 address legal rather than factual matters and characterize the Good Guidance Rule which is the best evidence of its content and to which no response is required.

127. The allegations in Paragraph 127 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

128. The allegations in Paragraph 128 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

129. The allegations in Paragraph 129 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

130. The allegations in Paragraph 130 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

131. The allegations in Paragraph 131 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

132. The allegations in Paragraph 132 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

133. The allegations in Paragraph 133 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

134. The allegations in Paragraph 134 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

135. The allegations in Paragraph 135 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

Count VIII—Violation of Administrative Procedure Act
The Advisory Opinion Is Contrary to Law and in Excess of Statutory Authority

136. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–136.

137. The allegations in Paragraph 137 address legal rather than factual matters and characterize the Administrative Procedure Act which is the best evidence of its content. To the extent that Paragraph 137 makes any material allegations that are inconsistent with the Administrative Procedure Act, they are denied.

138. The allegations in Paragraph 138 are conclusions of law to which no response is required and to which no response is required.

139. The allegations in Paragraph 139 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

140. The allegations in Paragraph 140 are conclusions of law to which no response is required. To the extent they may be deemed to be factual allegations, they are denied.

141. The allegations in Paragraph 141 are conclusions of law to which no response is required.

142. The allegations in Paragraph 142 are conclusions of law to which no response is required.

Count IX—Violation of Administrative Procedure Act
The Advisory Opinion Is Arbitrary and Capricious

143. Intervenors hereby incorporate their answers to the allegations in Paragraphs 1–142.

144. The allegations in Paragraph 144 address legal rather than factual matters and characterize the Administrative Procedure Act which is the best evidence of its content and to which no response is required.

145. The allegations in Paragraph 145 are conclusions of law to which no response is required and to which no response is required.

146. The allegations in Paragraph 146 are conclusions of law to which no response is required.

147. The allegations in Paragraph 147 are conclusions of law to which no response is required.

AFFIRMATIVE AND OTHER DEFENSES

1. Plaintiff fails to state a claim upon which relief may be granted.

2. The challenged December 30, 2020 Advisory Opinion issued by the General Counsel of HHS is consistent with and required by the 340B statute.

3. The challenged December 30, 2020 Advisory Opinion issued by the General Counsel of HHS does not violate the Administrative Procedures Act because it interprets a statutory requirement.

4. The challenged December 30, 2020 Advisory Opinion issued by the General Counsel of HHS is constitutional.

* * * * *

Intervenors reserve the right to amend their answer and defenses as more information is obtained.

Respectfully submitted,

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EXHIBIT C

Exhibit E

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July 17, 2020

BY E-MAIL

Eric Hargan, Esq.
Deputy Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Robert Charrow, Esq.
General Counsel
Department of Health and Human Services
200 Independence Avenue SW
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RE: 340B Contract Pharmacy Guidance

Dear Messrs. Hargan and Charrow,

On behalf of Eli Lilly and Company (Lilly), I am writing in response to communications submitted to Secretary Azar regarding Lilly's limited distribution program for Cialis (tadalafil) erectile dysfunction products.[1,2] Under that program, 340B covered entities and child sites receive 340B priced Cialis, but contract pharmacies do not unless an entity lacks an in-house pharmacy, in which case Lilly would voluntarily honor a contract pharmacy relationship. Our decision was arrived at after engagement between Lilly and the Health Resources and Services Administration (HRSA). We request a virtual meeting to discuss this matter with you at your earliest convenience and to identify options for avoiding costly and unnecessary litigation.

I. Background

On July 1, Lilly implemented a program, through wholesalers, to decline 340B contract pharmacy requests to acquire erectile dysfunction (ED) formulations of Cialis at the 340B ceiling price. The rationale for this decision was submitted to HRSA for prior review on May 18, 2020. See Attachment 1. On June 11, HRSA responded by stating that the Contract Pharmacy Guidance (75 Fed. Reg. 10,272 (Mar. 5, 2010)) is "advice" and is not binding on Lilly. HRSA encouraged Lilly to honor the guidance, citing a concern, *inter alia*, that some covered entities lacked an in-house pharmacy. Lilly responded to that communication on June 16 and, in deference to HRSA's concern, revised its proposal to accommodate entities without pharmacies. We submitted public notice of the program for review and posting by HRSA on June 26. We expect that HRSA fully reviewed the issue and its response with HHS before HRSA communicated its final determination to Lilly.

HRSA's determination that the contract pharmacy guidance is not legally binding, coupled with the fact the covered entities and child sites continue to have access to 340B priced product, ensures that Lilly is in compliance with the "must offer" provision and all other relevant aspects of the 340B statute. Lilly has and will continue to offer 340B price product to all 340B covered entities.

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[1] Michelle Stein, "340B Coalition To HHS: Stop Efforts By Lilly, Merck To Limit Discounts," Inside Health Policy. (July 16, 2020).

[2] We have addressed this communication to you because we understand that Secretary Azar has recused himself from matters regarding Eli Lilly and Company.

II. Implications for Federal Healthcare Programs and Patients

HHS is well acquainted with the 340B Program and its impact on the federal program finances.

Medicare Part B: In the 2018 Outpatient Prospective Payment (OPPS) rule, HHS attempted to adjust Medicare Part B reimbursement to 340B providers in acknowledgement of the fact that the standard reimbursement amount, Average Sales Price (ASP) plus 6% (4.3% during sequestration) results in excessive reimbursement on product acquired at a 340B prices and incentives for 340B covered entities to furnish higher priced products in higher cost settings.[3] 340B providers sued HHS to block this rule, as well as other Medicare cost-containment efforts intended to curtail excessive profiteering by hospitals at Medicare's expense.[4]

Medicare Part D: In 2019, the HHS OIG issued a report regarding Medicare Part D Rebates for Prescriptions filled at 340B Contract Pharmacies and found that, for just a sample of claims (554,549 reviewed in 2014), manufacturers would have paid rebates of up to $74.7 million more to Part D if those claims had not been 340B eligible. This occurs because manufacturers, under their contracts with Part D plan sponsors, typically are not responsible for Part D rebates on 340B-discounted utilization.[5] Moreover, as in the Part B context, the opportunity for a significant profit on 340B drugs, has led providers to steer patients to 340B sites of care or 340B product. These discounts covered by the definition of "negotiated price," causing Part D plans to reimburse 340B providers at rates well above their acquisition costs, sometimes fraudulently.[6]

Medicaid: In 2010, lobbyists for 340B covered entities were successful in inserting language in the Medicaid Drug Rebate statute to ensure that the right of 340B covered entities to receive discounts is superior to the right of Medicaid to receive rebates in the context of managed Medicaid utilization. This little noted provision reads:

> (j) Exemption of organized health care settings
>
> (1) Covered outpatient drugs are not subject to the requirements of this section [the Medicaid Drug Rebate statute] if such drugs are—
> (A) dispensed by health maintenance organizations, including Medicaid managed care organizations that contract under section 1396b(m) of this title; and
>
> (B) subject to discounts under section 256b [340B] of this title.

---

[3] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 59216 (Dec. 14, 2017).
[4] See, e.g., "Hospitals Sue HHS Over Negotiated Price Disclosure Rule," citing suits over site neutral payments and 340B payments. https://www.modernhealthcare.com/payment/hospitals-sue-hhs-over-negotiated-price-disclosure-rule (Dec. 4, 2019).
[5] HHS OIG, "Medicare Part D Rebates for Prescriptions Filled at 340B Contract Pharmacies," Report No. A-03-16-00002 (July 2019).
[6] *See* DOJ, *Kentucky Hospital to Pay over $10 Million to Resolve False Claims Act Allegations* (Nov. 20, 2019), *available at* https: //www.justice.gov/opa/pr/kentucky-hospital-pay-over-10-million-resolve-false-claims-act-allegations. (Alleging, for a 340B hospital and health center, that "Medicare Part D payers—often paid many multiples of the price paid by 'cash' payers for the same medication.") *See United States ex rel. Stone v. Jewish Hosp. & St. Mary's Healthcare, Inc., et al.*, Civil Action No. 3:17-294 (W.D. Ky.). Amended Complaint at 29.

42 U.S.C. 1396r-8(j) (brackets added). Given that nearly 70% of Medicaid beneficiaries are enrolled in a managed Medicaid plan, this provision likely results in either billions of dollars being siphoned away from Medicaid or hundreds of millions of dollars in duplicate discounts.[7]

Finally, Lilly conducted a patient survey to ensure that individual or uninsured patient out-of-pocket expenses would not be impacted. Based on that analysis, we believe that it continues to be the case the vast majority of patients only benefit indirectly from 340B profits generated by contract pharmacy utilization. There is no evidence that contract pharmacies are able to identify 340B patients at time of dispense nor are the 340B discounts extended, in whole or in part, to these patients.

III. Lilly's Proposal: Rescind the 2010 Contract Pharmacy Guidance

HHS has been asked by 340B Health and others to deem Lilly's Cialis distribution program a violation of the "must offer" provision. Were HHS to endorse this view, the Agency would be converting the Contract Pharmacy Guidance from an interpretive rule into a statement of law. The result would effectively render a nonbinding sub-regulatory guidance into a binding legislative rule in violation of the Administrative Procedures Act (APA). Any such pronouncement would also be a clear consummation of the Agency's decision-making process, immediately susceptible to a legal challenge.

If HHS takes no action and permits the HRSA interpretation to stand, 340B Health will likely either sue the Agency for withholding action it deems required or sue Lilly under a theory yet developed. In either case, HHS will be drawn into the matter as the underlying validity of the Contract Pharmacy Guidance is litigated.

To avoid litigation, we propose that HHS immediately rescind the Contract Pharmacy Guidance and, if HHS believes there is a statutory basis, to re-issue it as a formal regulation pursuant to notice and comment rulemaking. While we may question HHS's basis for asserting such authority, we believe that this would at least be procedurally consistent with the APA and consistent with recent Executive Orders (13,891 and 13,892) that (1) prohibit treating noncompliance with guidance as a violation unless there is a clear violation of statute or regulations and (2) require agencies to review their guidance documents and to withdraw those that lack the force and effect of law.

***

Lilly has profound concerns about the explosive growth of the 340B program and the lack of oversight and control over contract pharmacies in general. Simply put, it is not sustainable and manufacturers seeking to continue participating in the Medicaid Drug Rebate Program may be pushed out by the unchecked growth in 340B. Please contact me at hakim_anat@lilly.com to arrange for a time to meet to discuss this important issue.

Sincerely,

Anat Hakim
General Counsel, Eli Lilly and Company

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[7] Elizabeth Hinton, et al, 10 Things to Know about Medicaid Managed Care, (Dec. 16, 2019) https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-managed-care/

Attachment 1: Lilly's May 18, 2020 Letter to HRSA

Lilly USA, LLC

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By E-mail (KPedley@hrsa.gov)

May 18, 2020

Rear Admiral Krista M. Pedley
Director, Office of Pharmacy Affairs (OPA)
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Parklawn Building, Mail Stop 10C-03
Rockville, MD 20857

RE: Availability of 340B-Priced Cialis® (tadalafil) Erectile Dysfunction Presentations to Contract Pharmacies

Dear RADM Pedley:

Eli Lilly and Company (Lilly) is writing to inform the Health Resources and Services Administration (HRSA) that, effective July 1, 2020, we are instructing wholesalers to discontinue our practice of voluntarily honoring requests for 340B "contract pharmacies" for orders of certain Cialis® (tadalafil) presentations. Unless HRSA objects and states that it believes our proposed discontinuation of voluntary contract pharmacy 340B discounts is unlawful, providing us the reasons for its conclusions, Lilly will no longer honor contract pharmacy-related requests for 340B-priced purchases of the following products after that date: Cialis 10mg (00002-4463-30), Cialis 20 mg (00002-4464-30), and Cialis 2.5mg (00002-4465-34). In addition, and as discussed further below, Lilly is formally challenging HRSA's quarterly listings, which include contract pharmacy listings, pursuant to Section IV(b) of the Pharmaceutical Pricing Agreement (PPA). Under the PPA, we believe HRSA is obligated to respond to this letter.[1]

The presentations of Cialis at issue here are indicated solely for erectile dysfunction and are all available as generic formulations.[2] We are prepared to provide a public letter for posting on the HRSA website describing our discontinuation of voluntary contract pharmacy discounts.

7We believe this action is prudent, reasonable and lawful, particularly in light of the substantial and ongoing expansion of contract pharmacy participation in the 340B program and the now overwhelming evidence demonstrating that contract pharmacy transactions result in 340B duplicate discounts and diversion. Based on these concerns, coupled with the risk that contract pharmacy transactions may be considered a basis a Civil Money Penalties or subject to onerous repayment obligations, Lilly feels compelled to take this action at this time.

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[1] PPA § IV(b).

[2] In prior correspondence to HRSA, we articulated and explained our position, based on applicable statutory provisions, that presentations of Cialis that are indicated solely for erectile dysfunction are not "covered outpatient drugs" for purposes of the Medicaid Drug Rebate Program or the 340B Program and, thus, are not subject to the 340B ceiling price. *See* Lilly Letter to HRSA RE: CIALIS® (TADALAFIL) 340B CEILING PRICING (Mar. 17, 2015). Although we disagree with HRSA's assessment of the concerns we raised in that correspondence, we do not assert it as a basis at this time for our decision to cease voluntarily providing 340B discounts in connection with contract pharmacy purchases.

We explain, below, why Lilly does not believe 340B-priced purchases for contract pharmacies are consistent with or required by 42 U.S.C. § 256b (Section 340B). HRSA's 340B contract pharmacy guidance, 75 Fed. Reg. 10,272 (Mar. 5, 2010) (Contract Pharmacy Guidance), is inconsistent with the plain language of the statute and has resulted in systematic violations of the core requirements of Section 340B, as reflected in numerous audits and government reports. Further, developments after the issuance of the Contract Pharmacy Guidance demonstrate that the continued, wholesale adoption of the Contract Pharmacy Guidance is deeply flawed as a matter of public policy, both because HRSA has not considered subsequent statutory and regulatory developments and because the Contract Pharmacy Guidance is itself inconsistent with other guidance issued by HRSA. Most fundamentally, however, the Contract Pharmacy Guidance is both procedurally and substantively unlawful. We request that HRSA inform Lilly by June 17, 2020 if it objects to Lilly's proposed course of action.

Specifically, Lilly believes it has discretion to decline Section 340B contract pharmacy orders for at least the following reasons:

1. **Contract Pharmacy Arrangements Violate the Statutory Prohibition Against Diversion.**

The 340B statute is clear: "With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell ***or otherwise transfer the drug to a person who is not a patient of the entity***."[3] HRSA's Contract Pharmacy Guidance is inconsistent with this straightforward prohibition. In particular, the Contract Pharmacy Guidance, by its terms, requires the transfer of a drug to a legal person (typically a for-profit pharmacy) that is not a "covered entity" or a "patient."[4]

Clearly, a contract pharmacy is not a "covered entity." The plain language of Section 340B limits a manufacturer's obligation to offer 340B prices to "each covered entity."[5] In defining the term "covered entity," the statute states that it is "an entity" that "is one" of the specified entity types. Contract pharmacies are clearly not one of those "types."

---

[3] 42 U.S.C. § 256b(a)(5)(B) (emphasis added).

[4] The term "person" under Section 340B includes legal entities as well as individuals. "Under the Dictionary Act, 'the wor[d] "person" . . . include[s] corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals.'" *Burwell v. Hobby Lobby Stores, Inc*., 134 S. Ct. 2751, 2768 (2014); *see also FCC v. AT&T Inc*., 562 U.S. 397, 404-05 (2011) ("We have no doubt that 'person,' in a legal setting, often refers to artificial entities. The Dictionary Act makes that clear"); *Al Fayed v. CIA*, 229 F. 3d 272, 274 (D.C. Cir. 2000); *Soup, Inc. v. FTC*, 449 F. 2d 1142, 1143 (D.C. Cir. 1971) (per curiam) ("On the contrary, the statutory guidelines for the interpretation of Congressional acts, 1 U.S.C. § 1 (1970), make clear that the term "person" should ordinarily be taken to "include corporations * * * as well as individuals."). Moreover, here, the statutory "context" of Section 340B likewise confirms that the term "person" in the subsection prohibiting the "re[sale] or . . . transfer" of drugs under Section 340B "to a person who is not a patient of the entity" makes unlawful the "resale" or "transfer" of drugs under Section 340B to any non-patient of a covered entity, which necessarily includes ineligible "legal entities" as well as "individuals." 42 U.S.C. § 256b(a)(5)(B). Otherwise, "covered entities" could circumvent the prohibition against the resale or transfer of such drugs by simply transferring them to third party corporations on a wholesale basis. Such a reading would fundamentally undermine the program as designed by Congress and would be entirely inconsistent with the statutory scheme as a whole.

[5] 42 U.S.C. § 256b(a)(1).

Because the entities that Congress expected to participate in the program are listed, specifically, in the definition of "covered entity," the addition of contract pharmacies as a new category of recipients of covered outpatient drugs at 340B discount prices is prohibited.[6] The interpretive canon *expressio unius est exclusio alterius* requires that enumerated statutory lists must be read to exclude entities not expressly included.[7] Accordingly, by permitting contract pharmacies to participate in the program, we are concerned HRSA has exceeded its authority under Section 340B.[8]

HRSA has argued in the past, without statutory support, that contract pharmacies should receive 340B-discounted product because they should be deemed "agents" of covered entities.[9] We do not agree with the premise that contract pharmacies act as "agents" to covered entities. Further, the plain language of the statute forecloses this argument. The statute specifically limits a manufacturer's obligation to offer 340B discounted prices to "each covered entity," not to "each covered entity and its agents." The plain language of the statute defines the term "covered entity" to only mean "an entity" that "is one" of certain specified types. An agent of a covered entity is not the "entity" that "is one of the specified types."

Indeed, the statute *separately* refers repeatedly to numerous agents of different 340B program participants and principals, showing clearly that a reference to the principal is not a reference to the agent. For instance, the statute separately and distinctly refers to "covered entities" and agents of those covered entities, such as "associations or organizations representing the interests of such covered entities."[10] In fact, Section 340B separately refers to other participants and their agents repeatedly.[11]

The plain language of a statute must be read in context.[12] Here, the context shows that Congress identified when the 340B program applied to covered entities and various third parties, including those representing covered entities. Where, as here, Congress referred separately to principals and agents, when included, there is no basis to contend that references to covered entities include contract pharmacies.

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[6] *Id.* § 256b(a)(4).

[7] *See*, *e.g.*, *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1061 (D.C. Cir. 1995) ("[M]ention of one thing implies the exclusion of another thing"); *accord Independent Ins. Agents of America, Inc. v. Hawke*, 211 F. 3d 638, 644 (D.C. Cir. 2000); *American Methyl Corp. v. EPA*, 749 F.2d 826, 835-36 (D.C. Cir. 1984).

[8] This is especially true where contract pharmacies act as both "340B program administrator" and "340B contract pharmacy" for a given entity, suggesting that it is the for-profit commercial pharmacy that is the true beneficiary of the program and the 340B entity is effectively "renting out" its eligibility. https://www.walgreens.com/businesssolutions/payer/340BComplete.jsp.

[9] *See, e.g.*, 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996) (stating "[t]he contract pharmacy would act as an agent of the covered entity").

[10] 42 U.S.C. § 256b(d)(3)(B)(vi) (separately referring to "covered entities" and an agent of those covered entities, "associations or organizations representing the interests of such covered entities").

[11] 42 U.S.C. § 256b(d)(1)(B)(v) (referring separately to "wholesalers" contracted with manufacturers); *id*. § 256b(d)(2)(B)(iii) (referencing "distributors"); *id*. § 256b(d)(3)(B)(iii) (separately referring to manufacturers and "third parties" subject to discovery).

[12] *See Bell Atlantic Tel. Cos. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997) ("[T]extual analysis is a language game played on a field known as 'context.' The literal language of a provision taken out of context cannot provide conclusive proof of congressional intent, any more than a word can have meaning without context to illuminate its use. In short, 'the meaning of statutory language, plain or not, depends on context.'").

Congress's intent is all the more clear here. Congress has, over the course of 28 years, amended the 340B statute no fewer than four times, adding four types of covered entities through those amendments. Despite that, Congress has never chosen to recognize or codify HRSA's contract pharmacy guidance or the Agency's position that contract pharmacies may serve as "agents" of covered entities for purposes of 340B discounts.

Given, for all the reasons described above, that a contract pharmacy is not a covered entity, it is equally clear that by the very nature of the way contract pharmacies operate, their use necessarily involves a prohibited "transfer" of 340B discounted product to a non-340B covered entity, the contract pharmacy. As HRSA knows, contract pharmacies are dependent on virtual inventories and retrospective replenishment. These mechanisms necessarily involve a "transfer" of drug products to the contract pharmacies.

Under the "virtual inventory" systems and "retroactive replenishment" models that contract pharmacies use, the contract pharmacies do not segregate 340B inventory from non-340B inventory; rather, they have their own stock of inventory, purport to track dispensed prescriptions through a "virtual" inventory, and then supposedly *retroactively* seek to "replenish" product at 340B pricing for purchases allegedly determined—sometimes weeks or months after they are filled—to have been 340B-eligible. In other words, contract pharmacies dispense drugs *from their own stock*, and then determine later which prescriptions they will assert were 340B-eligible. For those prescriptions, they request—through an entirely retrospective process—replacement product at 340B pricing. The 340B product, which should only be dispensed to 340B patients, is then used, in reality, for non-340B patients.

Thus, these contract pharmacy operations necessarily constitute the transfer of 340B-discounted drugs to non-patients of the covered entity and, accordingly, are statutorily prohibited diversion. Agency guidance and interpretations are invalid and unlawful when they are inconsistent with the controlling statute.[13]

Indeed, the prohibited transfer of 340B product to non-340B patients under the replenishment model is not even consistent with HRSA's own guidance – in addition to its violating the statute. HRSA's "bill to/ship to" requirements are included in the Contract Pharmacy Guidance.[14] Under the "bill to/ship to" model required by HRSA, the covered entity should pay for the product to be used for 340B patients and the manufacturer may be directed to "ship to" the contract pharmacy.[15] Although we believe that this guidance is itself inconsistent with the statute, contract pharmacy transactions cannot be said to comply even with HRSA's existing guidance.

2. The Contract Pharmacy Guidance Is Unlawful, Ultra Vires, and Beyond HRSA's Statutory Authority.

The Contract Pharmacy Guidance results in direct harm to Lilly. By listing contract pharmacies among the entities eligible to obtain product priced at a Section 340B discount, HRSA applies this

[13] *See, e.g.*, *Gonzales v. Oregon*, 546 U.S. 243, 269-75 (2006) (invalidating an interpretive rule regulating medical practice on grounds that the agency interpretation was inconsistent with the controlling statute); *PhRMA v. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31, 54 (D.D.C. 2015) (invalidating HRSA's orphan drug exclusion "interpretive rule" because it was contrary to the language of Section 340B).
[14] *See* 75 Fed. Reg. at 10,277.
[15] *Id*.

Contract Pharmacy Guidance to Lilly, each quarter.[16] Unless HRSA rescinds the Contract Pharmacy Guidance or clarifies that it permits, but does not obligate, manufacturers to honor contract pharmacy orders, then those quarterly listings will continue to purport to obligate Lilly to provide Section 340B discounts to contract pharmacies, contrary to the statute. For the reasons cited in this letter, Lilly is formally challenging HRSA's quarterly listings pursuant to Section IV(b) of the Pharmaceutical Pricing Agreement (PPA).[17] Under the PPA, HRSA is obligated to respond.[18]

As a result of HRSA's actions, Lilly suffers injury and risk of loss when it provides, as dictated by HRSA, Section 340B discounts to entities that are not entitled to them. Indeed, as described below, the unlawful expansion of Section 340B through the Contract Pharmacy Guidance results in diversion of Section 340B drug sales, duplicate discounts in violation of Congress's commands in Section 340B, and other harm to State and Federal healthcare programs.[19]

To state the basis for our challenge under Section IV(b) of the PPA in greater detail, we believe that the Contract Pharmacy Guidance is ultra vires, beyond HRSA's statutory authority, and issued in violation of the Administrative Procedure Act (APA). The Guidance was not authorized under one of the defined areas for which Congress delegated rulemaking authority to HRSA. In addition, the quarterly listings and underlying Guidance, to the extent they should be interpreted as mandating 340B discounts on contract pharmacy transactions, represent a substantive change in the rights and obligations of affected parties, which HRSA has failed to promulgate by regulation, in violation of the APA. Finally, the guidance and any assertion or enforcement of its purported requirements is incompatible with the President's recent Executive Order and the Department of Justice's Brand Memorandum.

HRSA failed to comply with the APA's requirements for adopting substantive rules when it issued the Contract Pharmacy Guidance. The Contract Pharmacy Guidance is a "substantive," i.e., "legislative," rule because, as a result of it, HRSA "create[d] new law, rights or duties" for regulated parties under the 340B program.[20] Indeed, the Contract Pharmacy Guidance had a substantial "legal effect" on Lilly and other regulated entities because the expansion of Section 340B to include contract pharmacies imposed legal obligations, risks, and burdens on drug manufacturers, as well as on covered entities and contract pharmacies.[21] Thus, despite the label of a "guidance" document and the agency's assertion that the guidance does not create new rights or obligations for regulated

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[16] *See* Pharmaceutical Pricing Agreement, § III(a) ("Pursuant to the requirements under section 340B of the [Public Health Service] Act, the Secretary agrees to the following: (a) to make available a list of covered entities on the HRSA, Office of Pharmacy Affairs web site (http://www.bphc.hrsa.gov/opa/), or otherwise, for access by participating Manufacturers, covered entities, State Medicaid agencies, and the general public. This information will be updated, to the extent practicable, on a quarterly basis"), *available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/pharmaceutical-pricing-agreement-example.pdf.

[17] *See id*. § IV(b) ("The Manufacturer may challenge the presence of an entity on the list of eligible entities issued by the Secretary.")

[18] *Id.*

[19] *See* 42 U.S.C. § 256b(a)(5)(A) ("Prohibiting duplicate discounts or rebates"); *id.* § 256b(a)(5)(B) ("Prohibiting resale of drugs").

[20] *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (en banc); *see also Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec.*, 653 F.3d 1, 6-7 (D.C. Cir. 2011) ("The practical question inherent in the distinction between legislative and interpretive regulations is whether the new rule effects a substantive regulatory change to the statutory or regulatory regime.").

[21] *See PhRMA v. HHS*, 43 F. Supp. 3d at 46 (explaining that agency action is substantive rule where it affects "legal rights").

parties, *see* 75 Fed. Reg. at 10,273, the "guidance" was clearly a substantive rule. The massive growth in the number of contract pharmacies, the corresponding increase in 340B sales attributable to those purchases, and the evidence of diversion and duplicate discounts all underscore the substantive purpose and effect of the "guidance."[22] The fact that these transactions can also serve as a basis for Civil Money Penalties and/or require manufacturer repayments are further evidence that guidance has a substantive purpose and effect.

HRSA, however, did not comply with the procedural requirements that the APA imposes for substantive regulations.[23] In the Contract Pharmacy Guidance, HRSA acknowledged that it was not undertaking the procedure required for a legislative rule, asserting incorrectly that the regulatory action being taken was "exempt from notice and comment rulemaking under the APA."[24]

HRSA did not proceed through a substantive rulemaking, because it could not do so; it had and has no such authority. In *Pharm. Research & Mfrs. of Am. v. Dep't of Health & Human Servs*., 43 F. Supp. 3d 28 (D.D.C. 2014), the district court struck down a regulation adopted by HRSA that purported to implement a statutory provision. In that case, the district court held that HHS lacked authority to engage in such rulemaking. *Id.* at 31, 39. The court explained that HHS's authority to adopt regulations with respect to the 340B program was limited to discrete areas expressly specified in the 340B statute, and the court held that HRSA's limited regulatory authority did not extend to regulations interpreting or implementing the relevant provisions of Section 340B. Thereafter, the district court rejected HHS's effort to readopt the same policy as an interpretive rule. *See also Pharm. Research & Mfrs. of Am. v. Dep't of Health & Human Servs.,* 131 F. Supp. 3d 31 (D.D.C. 2015). Under this precedent, HHS lacks statutory authority to implement the Contract Pharmacy Guidance as it was not issued based on the limited authority provided by Congress.

Executive Order 13891 (Oct. 9, 2019), confirms that HRSA cannot impose substantive obligations on regulated parties through the Contract Pharmacy Guidance and HRSA's retention of the guidance violates the Order. Section 2 of the Executive Order 13891 explains that an agency may not regulate "the public without following the rulemaking procedures of the APA," and that "[e]ven when accompanied by a disclaimer that [the guidance] is non-binding, a guidance document issued by an agency may carry the implicit threat of enforcement action if the regulated public does not comply." In response, the Executive Order directs, among other things, that "it is the policy of the executive branch, to the extent consistent with applicable law, to require that agencies treat guidance documents as non-binding both in law and in practice . . . ."

Additionally, the Department of Justice likewise has confirmed that agency guidance documents may not be used to coerce regulated parties like Lilly into taking action or refraining from taking action beyond what is required by the terms of the applicable law or lawful regulation. *See* Rachel Brand, Associate Attorney General, Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases at 1 (Jan. 25, 2018) ("Brand Memo"). Under the Brand Memo, (1) "Guidance documents cannot create binding requirements that do not already exist by statute or regulation," (2) "the Department may not use enforcement authority to effectively convert agency guidance documents into binding rules," and (3) "noncompliance with guidance documents [should not be used as] a basis for proving violations of applicable law in [affirmative civil enforcement] cases." *Id.* at 2.

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[22] *See* notes 31-32, *supra.*
[23] *See* 5 U.S.C. § 553(b), (c) (setting forth agency obligations for notice-and-comment rulemaking).
[24] 75 Fed. Reg. at 10,273.

In some instances, HRSA representatives have sought to justify its authority to issue the Contract Pharmacy Guidance by stating that Section 340B does not prohibit these arrangements. That analysis ignores, however, that an agency may only exercise authority affirmatively granted by Congress. An unbroken line of D.C. Circuit Court of Appeals cases has steadfastly rejected the notion of "presuming" statutory authority because there is no express statutory prohibition against it.[25] This argument inverts the appropriate analysis. The question is not did Congress prohibit the Agency from taking an action; the question is did Congress specifically authorize that action.

3. The Contract Pharmacy Guidance Should Not Be Relied Upon or Enforced Because It Has Been Shown To Be Inconsistent with the Premise Upon Which It Was Issued.

When HRSA issued guidance permitting covered entities to enter into multiple contract pharmacy arrangements, with no numerical or geographical limitations, it rejected stakeholder concerns that unlimited contract pharmacy arrangements would necessarily result in diversion or statutorily prohibited Medicaid duplicate discounts.[26] In proposing the guidance, HRSA expressly asserted that, "[t]o date, there has been no evidence of drug diversion or duplicate manufacturer's discounts on 340B drugs" related to various contract pharmacy arrangements.[27] But, just as stakeholders feared and predicted, the available evidence makes clear that, as more and more prescriptions have been dispensed through contract pharmacies, diversion and duplicate discounts have resulted. We also are concerned that the breadth of penalties under the CMP Rule, under which HRSA may seek to assess a penalty of up to $5,000 per "instance of overcharge," would be vastly and unlawfully expanded by the inappropriate application of the Contract Pharmacy Guidance.

There are many reasons why the premise for the Guidance—HRSA's assumption that contract pharmacies would not lead to diversion and duplicate discounts—has failed. Unlike in-house pharmacies, contract pharmacies do not possess or have access to the records of the covered entity's patients sufficient to make a "patient" determination (even under the 1996 standards which are often themselves not followed by covered entities[28] or contract pharmacies[29]). Often "patient"

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[25] *See*, *e.g.*, *Aid Ass'n for Lutherans v. USPS*, 321 F.3d 1166, 1174 (D.C. Cir. 2003) (rejecting as "entirely untenable under well-established case law" the argument "that the disputed regulations are permissible because the statute does not expressly foreclose the construction advanced by the agency"); *ExxonMobil Gas Mktg. Co. v. FERC*, 297 F.3d 1071, 1088 (D.C. Cir. 2002) ("We have repeatedly admonished federal agencies that jurisdiction may not be presumed based solely on the fact that there is not an express withholding of jurisdiction."); *Nat'l Mining Ass'n v. U.S. Dep't of Interior*, 105 F.3d 691, 695 (D.C. Cir. 1997) (rejecting the "extreme position" that "because Congress did not specifically preclude" an agency action, the court "should defer to [the agency's] interpretation of the statute"); *Am. Petroleum Inst. v. EPA*, 52 F.3d 1113, 1120 (D.C. Cir. 1995) ("[W]e will not presume a delegation of power based solely on the fact that there is not an express withholding of that power."); *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1060 (D.C. Cir. 1995) ("We refuse ... to presume a delegation of power merely because Congress has not expressly withheld such power.").

[26] 75 Fed. Reg. at 10,273, 10,274 (noting comments raising concerns about diversion by contract pharmacies).

[27] 72 Fed. Reg. 1540, 1540 (Jan. 12, 2007).

[28] *See, e.g.*, *Genesis HealthCare v. Azar* No.:4-19-cv-1531-RBH (D.S.C. Dec. 18, 2019).

[29] *See, e.g.*, GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 2018) (discussing "identified noncompliance at contract pharmacies," including diversion findings in HRSA audits), *available at* https://www.gao.gov/assets/700/692697.pdf; OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 2014), at 1-2 ("We found that contract pharmacy arrangements create complications in preventing diversion, and that covered entities are addressing these complications in different ways. . . . In some cases, these different methods lead to differing determinations of 340B eligibility

determinations are adjudicated by contract pharmacies hastily, and/or inconsistently with 340B program standards, on the back end, after insufficient coordination with covered entities and consistent with an improper financial incentive to mischaracterize commercial customers as 340B "patients." Sprawling contract pharmacy networks are major sources of prohibited diversion, despite covered entities' obligations to police and oversee their contract pharmacy relationships.

Oversight agencies, including the Government Accountability Office (GAO) and Health and Human Services Office of Inspector General (HHS OIG), as well as Congressional committees, have all noted that the increased use of contract pharmacies has created substantial drug diversion and duplicate discount issues, problems, and violations. For example:

- 2011 GAO Report: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement: GAO concluded that "[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies." GAO further noted the "[i]ncreased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program".[30]

- 2014 HHS OIG Report: Contract Pharmacy Arrangements in the 340B Program: In 2014, HHS OIG reported that contract pharmacies create "complications" in preventing diversion because "some covered entities that do dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies did not report a method to avoid duplicate discounts." OEI-05-13-00431, at 1–2, *see also id*. at 16. HHS OIG also concluded, quite troublingly, that findings of noncompliance did not lead to HRSA terminating the covered entities' permission to use multiple pharmacy arrangements. *Id*. at 7, 9–15.

- 2018 HHS OIG Testimony: Examining Oversight Reports on the 340B Drug Pricing Program: In its testimony, OIG stated that it "has identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements." OIG Testimony Before the U.S. Senate Committee on Health, Education, Labor, and Pensions (May 15, 2018), at 5. OIG further stated that "many contract pharmacies dispense drugs to all of their customers—340B-eligible or otherwise—from their regular inventory."

- 2018 GAO Report: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement: In this report, GAO concluded that "[t]he *identified noncompliance* at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices."[31] For example, GAO found that approximately two-thirds (66 percent) of diversion findings in HRSA audits (from FY 2012 to FY 2017, based on results posted to HRSA's website as of February 2018), "involved drugs distributed at contract pharmacies."[32]

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across covered entities. That is, two covered entities may categorize similar prescriptions differently (i.e., 340B-eligible versus not 340B-eligible) in their contract pharmacy arrangements."), *available at* https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

[30] GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836: Published: Sep 23, 2011. Publicly Released: Sep 23, 2011. https://www.gao.gov/products/GAO-11-836 (emphasis added).

[31] GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 44 (June 2018), GAO-18-480, *available at* https://www.gao.gov/assets/700/692697.pdf (emphasis added).

[32] *Id.* at 44 & n. 64.

Despite this significant conclusion, GAO further noted that "the number of contract pharmacy oversight findings may be limited by the fact that officials from HRSA's contractor said that its auditors rely on verbal responses from entity officials about any internal review or self-audits conducted by the entity."[33]

- 2018 House Energy and Commerce Committee Report: Review of the 340B Drug Pricing Program: In 2018, the House Energy and Commerce Committee issued a report echoing the findings of HHS OIG, concluding that contract pharmacy arrangements lead to diversion of 340B drugs. The committee's review of HRSA's audit files revealed that many covered entities have engaged in diversion. Further, in one quarter of the audit files reviewed by committee staff, HRSA recommended that the covered entity improve its oversight of their contract pharmacy arrangement to prevent diversion of 340B drugs at the contract pharmacy. *See* H. Comm. on Energy & Commerce, at 39. The Committee emphasized its concerns by recommending that "[a]ll covered entities should perform independent audits of their contract pharmacies at regular intervals to ensure 340B program compliance." *Id.* at 76. The Committee endorsed auditing by manufacturers to stem unlawful diversions, underscoring how HRSA's limiting the actions that a manufacturer may take to police compliance undermines the program's integrity.

Publicly available audit statistics published by HRSA support these concerns. Notably:

Fiscal Year	Entity Audits	Entities with Contract Pharmacy Adverse Findings (All)	Entities with Contract Pharmacy Adverse Findings (Diversion)
2013	94	31	19
2014	104	45	34
2015	200	92	71
2016	200	77	61
2017	199	81	69
2018	200	64	42
2019	187	52	33

Finally, Lilly's own data demonstrate that contract pharmacies are a frequent source of noncompliance.

- 2013-2020 Analysis of Covered Entity and Contract Pharmacy Self-Disclosures: Over the past seven years, Lilly has received 125 disclosures in which contract pharmacy noncompliance was reported, involving either or both duplicate discounts and diversion.

- 2019 Contract Pharmacy Managed Medicaid Duplicate Discount Review: In 2019, Lilly engaged Kalderos, a third-party, to review Managed Medicaid rebate requests from five states (CA, LA, FL, TX and NJ) to identify instances of duplicate 340B discounts for selected covered entities from 2014 to 2018. Kalderos identified approximately $12.4M worth of duplicate discounts related to contract pharmacy utilization in connection with just this small sample.

[33] *Id.* at 44.

The statutory prohibitions against diversion and duplicate discounts are absolute and central to the program. HRSA should not—and manufacturers ought not to be required to—accept, year after year, report after report, and audit after audit, the ongoing violations of the Section 340B prohibitions against diversion and duplicate rebates involving contract pharmacies. Compelling evidence—including in government reports and congressional oversight hearings—demonstrate that the rampant growth of 340B transactions processed at or through contract pharmacies is an intractable problem. We believe that HRSA should, as a consequence, clarify, at a minimum, that manufacturers are not obligated to honor contract pharmacy-related orders for 340B-priced product.

4. The Contract Pharmacy Guidance Should Not Be Relied Upon or Enforced Because It Harms Other Federal and State Healthcare Programs.

There are also various ways in which the 340B Program in general, and contract pharmacies specifically, interfere with other federal healthcare programs.

Lilly has identified, as noted in greater detail above, widespread duplicate Medicaid discounts. Similarly, in January 2020, the Centers for Medicare & Medicaid Services (CMS) acknowledged the problem and noted that the burden of identifying duplicate discounts for contract pharmacy utilization falls onto the states:

> CMS is also aware that some states face challenges with avoiding duplicate discounts on 340B drugs dispensed by 340B contract pharmacies. Contract pharmacies may be unable to prospectively identify claims for 340B purchased drugs before billing states, because the prescriptions are not generally identified as 340B at the point of sale by the 340B covered entity. Collectively, states are responsible for retrospectively identifying claims, which is time consuming, often requires employing the services of contractors, and can be rather complex given the involvement of the number of contract pharmacies.[34]

The administrative burden placed on states and manufacturers to identify and resolve disputes because of the opaque and unreliable nature of contract pharmacy data is costly and time consuming. Moreover, because these disputed Medicaid rebates must be held in abeyance, states are denied Medicaid rebate payments pending resolution of these disputes, a process that can take years.

For example, concerns have been raised about diversion and the fact that contract pharmacies reduce Medicaid rebate payments to California's Medicaid program, Medi-Cal. As a consequence, these concerns have prompted the state's Legislative Analysts to consider whether lawmakers should prohibit or limit the dispensing of 340B drugs to Medi-Cal enrollees at contract pharmacies. The California Governor's 2018-2019 budget proposal sought to eliminate the use of 340B discounts in Medi-Cal and cited challenges in administering the federal Medicaid drug rebate program in conjunction with the 340B program (preventing prohibited duplicate discounts after the fact).[35] Our understanding is that consideration of the proposed prohibition is continuing.

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[34] CMCS Informational Bulletin, Best Practices for Avoiding 340B Duplicate Discounts in Medicaid (Jan. 8, 2020).

[35] The 2018-19 Budget: The Governor's Medi-Cal Proposal for the 340B Drug Pricing Program (Mar. 22, 2018), available at https://lao.ca.gov/reports/2018/3790/medi-cal-340B-032118.pdf.

In addition, with respect to the Medicare Part D program, we note that a 2019 HHS OIG report regarding Medicare Part D Rebates for Prescriptions filled at 340B Contract Pharmacies found that , for just a sample of claims (554,549 reviewed in 2014), manufacturers would have paid rebates of up to $74.7 million more to Part D if those claims had not been 340B eligible. This occurs because manufacturers, under their contracts with Part D plan sponsors, typically are not responsible for Part D rebates on 340B-discounted utilization.[36]

The risks and costs of contract pharmacy business practices to Federal and State healthcare programs further underscore why the Contract Pharmacy Guidance should be rescinded now or, at a minimum, why HRSA should publicly acknowledge that manufacturers have discretion to not follow that Guidance.

5. The Contract Pharmacy Guidance Should Not Be Relied Upon or Enforced Because It Conflicts with Other HRSA Guidance And Does Not Consider Subsequent Developments.

The Contract Pharmacy Guidance was published on March 5, 2010.[37] Although HRSA stated that it considered whether the Contract Pharmacy Guidance imposed additional burdens on manufacturers, HRSA could not have evaluated the impact of the Guidance in light of the Affordable Care Act (ACA), enacted on March 23, 2010, which fundamentally increased the burdens associated with this Guidance.

The ACA included a number of new provisions that subject manufacturers to potential liability for Civil Monetary Penalties (CMPSs) and a "repayment" obligation for mis-stated 340B ceiling prices. By expanding the purchases subject to 340B discount prices, the Contract Pharmacy Guidance imposed additional burdens as a consequence of the ACA provisions. These additional burdens were not contemplated or considered by HRSA when it adopted the Contract Pharmacy Guidance. Since HRSA has not evaluated the Contract Pharmacy Guidance in light of the ACA or the 340B CMP Rule, which became effective January 1, 2019, the Guidance should be rescinded.

HRSA should also rescind the Contract Pharmacy Guidance because it conflicts with other guidance issued by HRSA. Specifically, the Contract Pharmacy Guidance conflicts with both the guidance requiring 340B discounts to be asserted at the time of purchase and the "bill to/ship to" guidance. It is arbitrary and capricious for HRSA to maintain, without explanation, program requirements that are mutually inconsistent.[38]

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[36] A recent settlement also illustrates concerns related to the impact on the Medicare Part D Program. In November 2019, Jewish Hospital and St. Mary's Healthcare Inc., doing business as Pharmacy Plus and Pharmacy Plus Specialty, paid $10 million to settle claims that they overbilled Medicare Part D plans. *See* DOJ, *Kentucky Hospital to Pay over $10 Million to Resolve False Claims Act Allegations* (Nov. 20, 2019), *available at* https://www.justice.gov/opa/pr/kentucky-hospital-pay-over-10-million-resolve-false-claims-act-allegations. The whistleblower complaint in that case included allegations related to a hospital and health center's participation in the 340B program and, in particular, alleged that patients with third party insurance—"frequently including Medicare Part D payers—often paid many multiples of the price paid by 'cash' payers for the same medication." *See United States ex rel. Stone v. Jewish Hosp. & St. Mary's Healthcare, Inc., et al.*, Civil Action No. 3:17-294 (W.D. Ky.). Amended Complaint at 29.

[37] 75 Fed. Reg. 10,272 (March 5, 2010).

[38] *NCTA v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) (highlighting that agency is obligated to explain inconsistency in practice under the APA).

We do not believe there is any argument that the contract pharmacy "replenishment" models are consistent with other HRSA guidance. HRSA has clearly said that 340B covered entities "are responsible for requesting 340B pricing at the time of the original purchase."[39] The operation of 340B contract pharmacies contradicts that guidance.

In relevant part, the guidance provides:

> Does HRSA authorize covered entities to retroactively change a previous quarters' transactions from a non-340B transaction into a 340B price transaction . . . ?
>
> HRSA does not authorize covered entities to reclassify a purchase as 340B eligible after the fact. Covered entities participating in the 340B Program are responsible for requesting 340B pricing at the time of the original purchase. . . .[40]

Despite a clear prohibition on covered entities against reclassifying transactions after the time of purchase, this is exactly how contract pharmacies operate. There are multiple reports and audits that document that contract pharmacy purchases are "replenishment" orders, wherein a contract pharmacy does not assert the 340B price at the time that the product is actually dispensed to the purported 340B patient that receives that product. The assertion of a 340B price comes only many days or weeks or months later.[41] It is illogical that a covered entity would not be permitted to undertake such re-characterizations but that contract pharmacies, on behalf of themselves and/or covered entities, would be.

As discussed earlier in this letter, the contract pharmacy replenishment models also conflict with HRSA "bill to/ship to" guidance, which is explicitly incorporated into the Contract Pharmacy Guidance. These multiple conflicts constitute additional reasons that the Contract Pharmacy Guidance should not be seen as creating a mandate. Indeed, in our view, the Guidance should be rescinded or, at a minimum, clarified to confirm that manufacturers have discretion to not follow it.

* * *

We designate this letter as confidential, proprietary, and reflective of trade secrets. This letter contains confidential commercial and financial information within the meaning of the Freedom of Information Act (FOIA),[42] the relevant Federal criminal statute,[43] the FOIA regulations,[44] and other applicable laws, regulations, or policies. Specifically, this information is subject to exemption from

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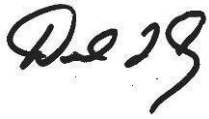
[39] *See* HRSA/OPA 340B FAQs, *at* https://www.hrsa.gov/opa/faqs/index.html (last visited April 21, 2020). HRSA, in its guidance, seems to hold out an exception to this rule where a covered entity notifies a manufacturer and secures the agreement of the manufacturer to the reclassification. Covered entities provide no such notice of contract pharmacy reclassifications, and Lilly would not, in any event, agree to them, as they are contrary to the statute for all the reasons discussed in this letter.
[40] HRSA/OPA 340B FAQs, *at* https://www.hrsa.gov/opa/faqs/index.html (last visited April 21, 2020).
[41] *See, e.g.*, OIG Testimony Before the U.S. Senate Committee on Health, Education, Labor, and Pensions (May 15, 2018); 80 Fed. Reg. 52,300, 52,308 (Aug. 28, 2015).
[42] 5 U.S.C. § 552.
[43] 18 U.S.C. § 1905.
[44] 17 C.F.R. § 200.83.

mandatory disclosure under Exemption 4 of FOIA,[45] and any other exemption applicable by law. Accordingly, we expect this letter and the documents contemplated by this letter will be kept in a non-public file and that HRSA will deny access to them by any unauthorized third person or entity. We also hereby request that your Office, department, and all constituent agencies provide notice to us of any request under FOIA for, or intended FOIA disclosure of, such information, records, or materials. This request is made pursuant to 5 U.S.C. §§ 552(b)(4), (6) & (7); 45 C.F.R. §§ 5.65(d), 5.67 & 5.68; Executive Order 12600; and Attorney General Ashcroft FOIA Memorandum (Oct. 12, 2001), *available at* http://www.justice.gov/archive/oip/foiapost/2001foiapost19.htm. Lilly also requests that reasonably prompt notice be provided to Lilly, at the contact information provided below, of any request by a third party for discovery of this letter, or of any proposal or apparent intention by a third party or your Office, department, or any constituent agency to enter this letter in the public record. We request that such notice be provided reasonably in advance of satisfying any such discovery request or, to the extent possible, that Lilly be enabled to seek confidential treatment of the letter or to seek relief in an appropriate court. These requests do not expire.

Please feel free to contact me at derek.asay@lilly.com directly if you have any questions or need any additional information. Thank you for your attention to this very important matter.

Sincerely,



Derek L. Asay
Senior Director, Government Strategy, Lilly USA

cc: Josh O'Harra, Assistant General Counsel, Eli Lilly and Company

[45] 5 U.S.C. § 552(b)(4).

EXHIBIT D

Exhibit C

From:	HRSA 340B Audit
To:	Derek L Asay
Cc:	Josh Tomas O"Harra
Subject:	[EXTERNAL] Response to Derek L Asay - Eli Lilly USA - 00002 - Availability of Cialis-Tadalafil - 06-11-2020
Date:	Thursday, June 11, 2020 1:34:09 PM
Attachments:	image001.png

Mr. Derek L. Asay
Senior Director, Government Strategy
Lilly USA, LLC
Lilly Corporate Center
Indianapolis, Indiana 46285

Dear Dr. Siegel:

The Health Resources and Services Administration (HRSA) is responding to Lilly USA's (Lilly) May 18, 2020, correspondence regarding contract pharmacies in the 340B Drug Pricing Program (340B Program). Many of the arguments advanced in Lilly's letter are not persuasive, and we do not address the arguments here. Our primary point is the importance for manufacturers to observe the guidance so that the program can meet its statutory objectives. Contract pharmacies, which are only a mode for dispensing 340B drugs and not independent covered entities, serve a vital function in covered entities' ability to serve underserved and vulnerable populations. Therefore, HRSA strongly encourages Lilly to reconsider its decision to discontinue contract pharmacy 340B discounts.

Many health centers and other safety net organizations receiving HRSA grants do not have an in-house pharmacy and are able to participate in the 340B Program only through a contract pharmacy. Lilly's position, especially if expanded to other drugs, would have the effect of denying underserved and vulnerable populations served by these covered entities access to 340B discounted drugs. This result would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute. [1] Even for those covered entities with in-house pharmacies, Lilly's refusal to honor contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy as a critical point obtaining their prescriptions.

While HRSA has published contract pharmacy advice in guidance, rather than through binding regulations, HRSA strongly encourages Lilly to reconsider its position. Lilly's refusal to sell 340B priced drugs to covered entities through contract pharmacy arrangements would have a significant negative impact on the nation's safety net, especially at a time when the health care community is under great pressure to address the current COVID-19 pandemic. We note that the contract pharmacy guidance was issued only after notice and public comment, and that stakeholders had the opportunity to address any concerns about the scope of the guidance before its final adoption.

Lilly indicated in its letter that it considers its letter to be "confidential and proprietary not subject to release or disclosure under FOIA or otherwise." HRSA fails to see any confidential

or proprietary information in the letter. If Lilly believes that portions of its correspondence are confidential or proprietary, please respond with an explanation and reference to the specific portions of the letter that Lilly believes are confidential and proprietary.

Sincerely,

Krista M. Pedley, PharmD, MS
RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
Email: 340baudit@hrsa.gov

cc: Josh O'Harra, Assistant General Counsel, Eli Lilly and Company

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[1] The intent of the 340B Program is to permit covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. (See: [1] See: H.R. REP No. 102-384(II), at 12 (1992) (Conf. Report).

EXHIBIT E

Exhibit G

Limited Distribution Plan Notice for Eli Lilly and Company Products

This notice provides information to 340B eligible covered entities seeking to purchase any product manufactured or distributed by Eli Lilly and Company or its subsidiaries and affiliates (labeler codes 00002, 00077, and 66713).Effective September 1, 2020, Lilly is limiting distribution of all 340B ceiling priced product directly to covered entities and their child sites only. Covered Entities will not be eligible to purchase Eli Lilly and Company products at the 340B ceiling price for shipment to a contract pharmacy.

Covered entities that do not have an in-house pharmacy may contact 340B@lilly.com regarding the exception process to designate a contract pharmacy location.

Special Exception for Insulins: Contract Pharmacies that Pass on 340B Discounts

Consistent with the spirit of Executive Order 13,937, "Access to Affordable Life-saving Medications" (July 24, 2020), Lilly will grant an exception to the limited distribution program described above for Lilly insulin products (NDCs attached) subject to a 340B covered entity and their contract pharmacys' ability to ensure that the following conditions are met:

- Any and all 340B eligible patients will be able to acquire their Lilly insulins through the contract pharmacy at the 340B price (typically $.03 per 3 mL pen or $.10 per 10 mL vial) at the point-of-sale;

- Neither the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing fee for the Lilly insulin;

- No insurer or payer is billed for the Lilly insulin dispensed; and,

- The covered entity provides claim-level detail (CLD) demonstrating satisfaction of these terms and conditions.

Lilly shares the goal of ensuring that 340B patients directly benefit from the significant 340B discounts on Lilly insulins.

To take advantage of this exception for insulins contact 340B@lilly.com. Please be prepared to submit documentation demonstrating that the conditions set forth above will be satisfied. Lilly is committed to compliance with the 340B statute and to responsible distribution of its products. If you have any questions regarding this notice please contact Lilly at 340B@lilly.com.

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Special Exception for Insulins:
Contract Pharmacies that Pass on 340B Discounts Applicable NDCs

NDC	Brand Name	Product Description
00002-7510-01	HUMALOG	HUMALOG 100UCD 10.000000 MML
00002-7510-17	HUMALOG	HUMALOG 100UCD 3 MILLILITER
00002-7516-59	HUMALOG	HUMALOG CARTRIDGE 100UCD 15.000000 MML
00002-7714-59	HUMALOG	HUMALOG JR KWIKPEN 100UCD 15 MILLILITER
00002-8799-59	HUMALOG	HUMALOG KWIKPEN 100UCD 15 MILLILITER
00002-7511-01	HUMALOG	HUMALOG MIX 75/25 100UCD 10 MILLILITER
00002-7512-01	HUMALOG	HUMALOG MIX50/50 100UCD 10 MILLILITER
00002-8798-59	HUMALOG	HUMALOG MIX50/50 KWIKPEN 100UCD 15 MILLILITER
00002-8797-59	HUMALOG	HUMALOG MIX75/25 KWIKPEN 100UCD 15 MILLILITER
00002-8824-27	HUMULIN R U500	HUMULIN 500 UCD 6.000000 MILLILITER
00002-8501-01	HUMULIN R U500	HUMULIN R 500UCD 20 MILLILITER
00002-7737-01	INSULIN LISPRO	INSULIN LISPRO 100 UCD 10.000000MILLILITER
00002-7752-05	INSULIN LISPRO	INSULIN LISPRO KWIKPEN JR 100UCD 15 MILLILITER
00002-8222-59	INSULIN LISPRO	INSULIN LISPRO KWIKPEN 100UCD 15.000000 MILLILITER
00002-8233-05	INSULIN LISPRO	INSULIN LISPROMIX75/25 KWIKPEN 100UCD 15 MILLILITER
66733-0773-01	INSULIN LISPRO	INSULIN LISPRO 100 UCD 10.000000 MILLILITER
66733-0822-59	INSULIN LISPRO	INSULIN LISPRO 100 UCD 15.000000 MILLILITER

EXHIBIT F

Exhibit A

Date: August 17, 2020

Re: 340B Contract Pharmacy Pricing

Dear Valued Partner,

AstraZeneca to date has processed chargebacks associated with Contract Pharmacy arrangements consistent with the approach proposed in the Health Resources and Services Administration's ("HRSA") April 2010 guidance. Beginning on October 1, 2020, AstraZeneca plans to adjust this approach such that AstraZeneca only will process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy.

To implement this new approach, AstraZeneca will stop processing 340B chargebacks for all 340B Contract Pharmacy arrangements effective October 1, 2020. Any 340B Covered Entity that does not have an outpatient, on-site dispensing pharmacy should contact AstraZeneca to arrange for a Contract Pharmacy of its choice to be eligible to receive 340B pricing on behalf of the Covered Entity. To initiate this process, please contact Membership@AstraZeneca.com.

340B Pricing for Contract Pharmacies will be honored on all invoices, consistent with AstraZeneca's historic approach, through September 30, 2020. For additional information or questions, please contact your AstraZeneca Account Director.

Sincerely,

DocuSigned by:
0781790EE5034A7...

Odalys Caprisecca
Executive Director, Strategic Pricing & Operations

EXHIBIT G

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

The General Counsel
Washington, D.C. 20201

ADVISORY OPINION 20-06 ON CONTRACT PHARMACIES UNDER THE 340B PROGRAM
DECEMBER 30, 2020

The 340B Program, established by section 340B of the Public Health Service Act ("PHSA"), 42 U.S.C. § 256b, imposes limitations on the prices manufacturers may charge for medications sold to specified health care facilities, referred to as "covered entities." Those facilities include public hospitals and community health centers, many of which provide safety-net services to the poor. The 340B Program requires drug manufacturers, as a condition of coverage of their products under Medicaid (*see* Social Security Act ("SSA") § 1902(a)(54)) and Medicare Part B (*see, e.g.*, SSA §§ 1842(o)(1), 1847A), to agree to sell their covered outpatient drugs to covered entities at no more than the statutorily-set "ceiling price." *See* SSA § 1927(a)(1).

Many covered entities enter into written agreements with pharmacies ("contract pharmacies") to distribute their covered outpatient drugs to the entities' patients. Under those agreements, the covered entity orders and pays for the 340B drugs, which are then shipped from the manufacturer to the contract pharmacy. Although the contact pharmacy has physical possession of the drug, it has been purchased by the covered entity.

Recently, certain drug manufacturers participating in the 340B Program are declining to distribute covered outpatient drugs through contract pharmacies at the ceiling price.

The Office of the General Counsel ("OGC") has received numerous requests from both manufacturers and covered entities to address whether it is proper for a drug manufacturer participating in the 340B Program to refuse to provide covered outpatient drugs at the 340B ceiling price to a covered entity for drugs distributed at the entity's contract pharmacies. For the reasons set forth below, we conclude that to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs.

I. Analysis

A. The Plain Meaning of Section 340B Requires Manufacturers to Sell Covered Drugs to Covered Entities at or Below the Ceiling Price, Independent of Whether the Entity Opts to Use Contract Pharmacies to Dispense the Drugs

"[O]ur inquiry begins with the statutory text, and ends there as well if the text is unambiguous." *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004). Section 340B of the PHSA, entitled "Limitation on prices of drugs purchased by covered entities," states, in relevant part, that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." 42 U.S.C. § 256b(a)(1) (emphasis supplied). Furthermore, "[e]ach such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* As a result, the obligations placed on manufacturers by 340B are set out in a Pharmaceutical Pricing Agreement ("PPA") between the Secretary and the respective manufacturer. *See generally Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110 (2011) (describing role of PPAs in 340B Program). The exemplar PPA provides, in pertinent part, as follows:

> Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following: (a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed an amount equal to [the ceiling price].

PPA § II(a). The exemplar PPA Addendum provides that a "[m]anufacturer shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price, if such drug is made available to any other purchaser at any price." PPA Addendum ¶ 2.

Thus, the core requirement of the 340B statute, as also reflected in the PPA and Addendum, is that manufacturers must "offer" covered outpatient drugs at or below the ceiling price for "purchase by" covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. All that is required is that the discounted drug be "purchased by" a covered entity. In this setting, neither the agency nor a private actor is authorized by section 340B to add requirements to the statute. *See Radovich v. Nat'l Football League*, 352 U.S. 445, 454 (1957) ("Congress itself has placed the private antitrust litigant in a most favorable position . . . . In the face of such a policy this Court should not add requirements to burden the private litigant beyond what is specifically set forth by Congress in those laws."); *Financial Planning Ass'n v. SEC,* 482 F.3d 481 (D.C. Cir. 2007); *Baker v. Bell Textron, Inc.*, 2020 WL 5513431, at *4 (N.D. Tex. 2020) ("The Court will not add requirements to the law that Congress could have included but did not.").

It is against this backdrop that we examine the 340B phrase "purchased by." It is difficult to envision a less ambiguous phrase and no amount of linguistic gymnastics can ordain otherwise. The Court recently cautioned against seeing ambiguity where none exists. For

example, a regulation must be "genuinely ambiguous" before resorting to deference. *Kisor v. Wilkie*, ___U.S.___, 139 S.Ct. 2400, 2415 (2019). Here, as we understand it, the medications at issue are sold by the manufacturer to the covered entity; the covered entity takes title and the covered entity pays the manufacturer either directly or through the manufacturer's distributor. In either event, the arrangement between the manufacturer and covered entity is a straightforward "sale" which "consists of the passing of title from the seller [drug manufacturer] to the buyer [covered entity] for a price." Uniform Commercial Code (U.C.C.) § 2-106.[1] A "buyer" is, by definition, a "purchaser." BLACK'S LAW DICTIONARY (11th ed. 2019) (defining "buyer" as "[s]omeone who makes a purchase"). The situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant. *See* U.C.C. § 2-401(2) ("Unless otherwise explicitly agreed title passes to the buyer at the time and place at which the seller completes his performance with reference to the physical delivery of the goods . . . ").

Given the lack of ambiguity in the plain text of the statute, the above analysis is dispositive. *Bostock v. Clayton Cty.*, ___U.S.___, 140 S. Ct. 1731, 1739 (2020) ("[W]hen the meaning of the statute's terms is plain, our job is at an end."). This straightforward textual interpretation, aside from dutifully reflecting the plain meaning of the statute, has the added benefit of comporting with the statute's purpose and history.

B. The Purpose and History of the 340B Program Reflect the Provision's Plain Meaning

1. Contract Pharmacies Have Been an Integral Part of the 340B Program Since Its Outset

The 340B Program was created to allow covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rept. No. 102–384(II), at 12 (1992). As the Health Resources and Services Administration ("HRSA")—the agency primarily responsible for administering the 340B Program—has explained in prior guidance, a substantial number of covered entities are practically constrained to rely on contract pharmacies to access the 340B Program; if manufacturers can simply shut off this means of access, the Program's effectiveness will be greatly diminished. *See Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996); *see also Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 84 Fed. Reg. 2340 (proposed Feb. 6, 2019) (OIG proposed rule discussing distribution of pharmaceuticals).[2]

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[1] The U.C.C. can be used for statutory construction, even if it does not directly apply. *See Comm'r of Internal Revenue v. Brown*, 380 U.S. 563, 571 (1965) (interpreting provision of the Internal Revenue Code by pointing to U.C.C. as support for the "ordinary sense" of the word "sale").

[2] The argument that the statute also evinces a purpose to prevent drug diversion or duplicate discounting, and therefore prohibits contract-pharmacy arrangements, is not persuasive. That is like arguing that the main purpose of federal healthcare programs are their antifraud provisions. In the absence of the core 340B discount mechanism, there would be no need for the duplicate-discount or diversion provisions.

This is particularly pertinent given that at the outset of the 340B Program only approximately 500 out of 11,500 covered entities (less than 5 percent) used in-house pharmacies. *See* 61 Fed. Reg. at 43,550. This is not surprising: the Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations. *See, e.g.*, 42 U.S.C. § 256b(a)(4) (defining covered entities); *Astra USA*, 563 U.S. at 113. These are the poster children of providers that one would expect to lack an in-house pharmacy. To champion a policy, ungrounded in the language of the statute, that would foreclose 340B discounts to 95 percent of covered entities and foreclose discounts to the neediest of this cohort is inconsistent with purpose of the Program and common sense. Had Congress intended to reach such a bizarre result, it would have used language affirmatively precluding the use of contract pharmacies as arms in the distribution channel, but it did not. *Doe v. Hesketh*, 828 F.3d 159, 167 (3d Cir. 2016) (the result is "so bizarre that Congress could not have intended it").

2. The Department's Longstanding Interpretation of Section 340B Reflects the Plain Language of the Section by Recognizing the Use of Contract Pharmacies

The Department's longstanding interpretation of the statute, as expressed through guidance, is that manufacturers are required to offer ceiling prices even where contract pharmacies are used. In 1996, HRSA issued the aforementioned guidance and stated, "[i]t has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price." 61 Fed. Reg. at 43,549. HRSA's assertion cannot be attacked as impermissible legislative rulemaking,[3] because the guidance only sought to "explain the statutory language by clarifying the meaning given by the Department to particular words or phrases"—it "create[d] no new law and create[d] no new rights or duties" not otherwise present in the statute. *See id.* at 43,550. HRSA reaffirmed its interpretation of the statute in guidance issued in 2010. *See* HRSA, *Notice Regarding 340B Drug Pricing Program–Contract Pharmacy Services*, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

The Department's consistent position over the past 24-plus years would factor into a court's interpretation of the statute. Courts defer to agency expertise in the interpretation of statutes, especially where they govern complex administrative regimes. *See, e.g.*, *United States v. Mead Corp.*, 533 U.S. 218, 227–28 (2001). Conversely, a court would be skeptical of an abrupt about-face. *See, e.g.*, *Wyeth v. Levine*, 555 U.S. 555, 577–81 (2009). Courts may also look to agency implementation and the actions of regulated parties to determine the meaning of a statute. *See, e.g.*, *S.D. Warren Co. v. Me. Bd. of Env't Prot.*, 547 U.S. 370, 377–78 (2006) (even though relevant agencies had not "formally settled the definition, or even set out agency reasoning," the "administrative usage of [the disputed term] in this way confirm[ed the Court's]

[3] *See, generally*, *Pharm. Rsch. and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014) ("Within section 340B, Congress specifically authorized rulemaking in three places: (1) the establishment of an administrative dispute resolution process, (2) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions."); *Pharm. Rsch. and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs.*, 138 F. Supp. 3d 31, 39 (D.D.C. 2015) (even if "HHS lacks the authority to promulgate the rule as a binding statement of law, HHS is not forbidden altogether from proffering its interpretation of the statute").

understanding"); *Bd. of the Trs. of Leland Stanford Jr. Univ. v. Roche Molecular Sys.*, 563 U.S. 776, 792–93 (2011) ("[I]t is worth noting that our construction of the [statute in question] is reflected in the common practice among parties operating under the Act."). Here, contract-pharmacy arrangements have been utilized, and honored by manufacturers, since 1996 and earlier.[4]

C. Manufacturers' Rationale for Precluding the Use of Contract Pharmacies Is Not Supported by the Language of the Statute and Leads to Absurd Results

The primary rationale offered for cutting off contract pharmacies—that such arrangements lead to a heightened risk of diversion and duplicate discounts—makes clear that manufacturers are attempting to circumvent section 340B's procedures for resolving disputes between manufacturers and covered entities. *See, e.g.*, *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1984) ("In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole.") (emphasis supplied). Not surprisingly, the manufacturers have been unable to point to any language in the statute that would support this hobbling interpretation. If a manufacturer is concerned that a covered entity has engaged in duplicate discounting or diversion, *see* 42 U.S.C. § 256b(a)(5)(A), (B), it must (1) conduct an audit, and (2) submit the claim to the administrative dispute resolution ("ADR") process, *see* §256b(d)(3)(A). The PPA even provides that a covered entity's failure to comply with the audit requirement does not "relieve the Manufacturer from its obligation to conform to the pricing requirements as provided in section 340B(a) of the Act and the Agreement." PPA § IV(d). Moreover, the Department specifically rejected this reasoning when issuing regulations regarding the calculation of the 340B ceiling price. In responding to a comment regarding perceived 340B violations, HRSA stated "[m]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity." *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017). In addition, "[m]anufacturers that suspect diversion are encouraged to work in good faith with the covered entity, conduct an audit per the current audit guidelines, or contact HHS directly." *Id.* Certain manufacturers' newfound and unilateral refusal to sell drugs through contract pharmacies is at odds with the structure and intended operation of the statute.[5]

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[4] The fact that Congress has not amended the 340B statute to expressly exclude contract-pharmacy arrangements from coverage can be read as supporting the agency's longstanding construction. *See* Valerie C. Brannon, Cong. Rsch. Serv., R45153, *Statutory Interpretation: Theories, Tools, and Trends* 63 (2018) (discussing "presumption of legislative acquiescence").

[5] For 24-plus years, manufacturers have offered the ceiling price to covered entities using contract-pharmacy distribution. To the extent manufacturers now have sincere concerns about diversion or duplicate discounting, the 340B statute speaks directly to how they should proceed. *See also 340B Drug Pricing Program; Administrative Dispute Resolution Regulation*, 85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020) ("The purpose of the ADR process is to resolve . . . claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibition on diversion or duplicate discounts."). Manufacturers who shut off contract-pharmacy access may have also skipped over any effort to resolve disputes with covered entities in "good faith." PPA § IV(a)(1) ("If the Manufacturer believes that a covered entity has violated the prohibition against resale or transfer of covered outpatient drugs, section 340B(a)(5)(B), or the prohibition against duplicate discounts or rebates, section 340B(a)(5)(A) . . . [t]he Manufacturer shall attempt in good faith to resolve the matter with the covered entity."); 85 Fed. Reg. at 80,633 ("Historically, HHS has

Relatedly, it has also been argued that the use of contract pharmacies is inconsistent with the 340B statute's prohibition on diversion of discount drugs. We start with the basic proposition that subsection (a)(5)(B) was intended to prohibit the diversion of 340B drugs. *See* 42 U.S.C. § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."). According to one court, the 340B Program places a "ban on 'diversion,' *i.e.*, a requirement that covered entities refrain from reselling or otherwise transferring covered drugs to non–340B entities[.]" *Cty. of Santa Clara v. Astra USA, Inc.*, 257 F.R.D. 207, 211–12 (N.D. Cal. 2009), *vacated on other grounds*, *Astra USA,* 563 U.S. 110; *see also* 85 Fed. Reg. at 80,636 (subsection (a)(5)(B) prohibits diversion).

Diversion means that, on net, covered outpatient drugs end up in the hands of persons who are not patients of the covered entity. The movement of drugs purchased by the covered entity and ultimately dispensed to the patient by a contract pharmacy can involve complex inventory models. Whether diversion occurs, however, should be independent of the inventory-accounting model contemplated by the agreement between the contract pharmacy and the covered entity. *See Toyota Motor Sales, U.S.A., Inc. v. United States,* 35 Ct. Int'l Trade 1205 (2011) (noting that inventory-accounting methods are authorized to determine tariffs and drawbacks); *Sears, Roebuck & Co. v. King County*, 487 P.2d 221, 223, 5 Wash. App. 273, 276 (1971) (for tax purposes "identification by any reasonable and reliable [inventory-accounting] method [is proper], rather than by a strict tracing method.").

The notion that the legitimate transfer of drugs to contract pharmacies so that they can be dispensed to patients of the covered entity constitutes diversion not only ignores the realities of accounting, but also that the covered entity and contract pharmacy are not distinct, but function as principal-agent. As explained, the covered entity remains the purchaser whether it chooses to have discount drugs distributed through an in-house pharmacy or a contract pharmacy. *See also* 61 Fed. Reg. at 43,550 ("The mechanism does not in any way extend this pricing to entities which do not meet program eligibility."); *id.* (agreeing that "[a]s a general rule, a person or entity privileged to perform an act may appoint an agent to perform the act unless contrary to public policy or an agreement requiring personal performance") (citing Restatement (Second) of Agency § 17 (Am. L. Inst. 1995)); *id.* ("The contract pharmacy would act as an agent of the covered entity, in that it would not resell a prescription drug but rather distribute the drug on behalf of the covered entity. This situation is akin to a covered entity having its own pharmacy."); *id.* at 43,552 (under "bill to/ship to" arrangement contemplated in guidance, "[t]he contract pharmacy does not purchase the drug. Title to the drugs passes to the covered entity" and "the manufacturer is still selling to the covered entities"); *cf. Abramski v. United States*, 573 U.S. 169, 186 (2014) ("[t]he individual who sends a straw [purchaser] to a gun store to buy a firearm is transacting with the dealer, in every way but the most formal" such that "straw arrangements are not a part of the secondary market, separate and apart from the dealer's sale") (emphasis in original).[6]

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encouraged manufacturers and covered entities to work with each other to attempt to resolve disputes in good faith.").

[6] Similar reasoning still applies under the so-called "replenishment" model, where the contract pharmacy dispenses medications from a general inventory to the covered entity's patient and "replenishes" its general

In addition, the argument that use of contract pharmacies constitutes an illicit "transfer" leads to absurd results. For instance, if a covered entity uses a courier service to send discount drugs to its patient, this, too, would be appear to be an illegal "transfer" to the shipper. Any arrangement that did not involve a physical hand-off from the employee of a covered entity to the patient him or herself could be an unauthorized "transfer" under the 340B statute. To avoid such absurdities, and under the canon of *noscitur a sociis*,[7] the phrase "otherwise transfer" must be interpreted in conjunction with the word "resell" and the title of that specific provision ("Prohibiting resale of drugs") (emphasis supplied).[8]

This conclusion is reinforced by an understanding of the practical realities of drug distribution. Such distribution often functions through intermediaries. For example, covered entities often purchase 340B discounted drugs from wholesalers, not directly from manufacturers. And yet, the obligations of § 256b(a) are placed on manufacturers. If it were correct that distribution to any entity other than a covered entity freed the manufacturer from the obligation to charge no more than the ceiling price, then there would be no firm basis for the wholesalers to charge-back discounts to the manufacturer. Large portions of the current 340B Program would seem to turn on solely manufacturers' voluntary choice to offer the ceiling price,

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inventory with discount medications purchased by the covered entity. The inventory commingling (drugs purchased by covered entity(ies) under the auspices of 340B, commingled with what the contract pharmacy might otherwise have) does not change the analysis. *Cf. Martin Marietta Corp. v. N.J. Nat'l Bank*, 612 F.2d 745, 749 (3d Cir. 1979) ("identification" of goods for purposes of U.C.C. § 2-501 not broken even if "seller removes some of the fungibles and later replaces them . . . because such conduct is quite natural with fungibles and cannot be taken as an intent to negate the buyer's interest in the goods"); *Apex Oil Co. v. Belcher Co. of N.Y., Inc.*, 855 F.2d 997, 1,003–05 (2d Cir. 1988) ("[W]here fungible goods are concerned, identification is not always an irrevocable act and does not foreclose the possibility of substitution."); *Matter of Bevill, Bresler & Schulman Asset Mgmt. Corp.*, 67 B.R. 557, 588 (D.N.J. 1986) (under U.C.C. § 9-207, "a secured party is allowed to commingle fungible collateral, including certain types of securities, and may sell the collateral and replace it with instruments which are equivalent in kind and value without breaching his duty to exercise reasonable care in the custody and preservation of the pledged collateral"). Nor does the ordering of events. If the contract pharmacy's dispensing of the drugs is event "A" and the contract pharmacy's receipt of the drugs is event "B," the ordering of events does not matter if repeated over time. Whether the series looks like ...BABABA... or ...ABABAB... is simply a function of the reference timeframe. In sum, where the contract pharmacy is replenished by the covered entity and dispenses to the covered entity's patients on a rolling basis, it is still true that the covered entity's patients are receiving the covered entity's drugs—they are not re-sold or "otherwise transfer[red]" to the contract pharmacy.

It also bears mention that the replenishment inventory model is currently an integral part of many patient assistance programs operated by drug manufacturers. *See, e.g.*, *Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70,623, 70,624 (Nov. 22, 2005); Merck & Co., Inc. *For Health Care Professionals*, MERCK HELPS, https://www.merckhelps.com/HCPs.aspx (last visited Dec. 21, 2020); Pfizer, Inc., *The Pfizer Institutional Patient Assistance Program (IPAP) At-a-Glance* (April 2019), https://www.pfizerrxpathways.com/sites/default/files/attachment/PP-PAT-USA1032%20RxPathways_IPAP_Factsheet%202019.pdf (last visited Dec. 21, 2020).

[7] "[W]e rely on the principle of *noscitur a sociis*—a word is known by the company it keeps—to avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress." *Yates v. United States*, 574 U.S. 528, 543 (2015) (plurality op.) (quotes omitted).

[8] An exact delineation of the scope of the phrase "otherwise transfer" is beyond the scope of the Advisory Opinion. The point here is simply that the phrase must have some limiting principle to avoid sweeping in innocuous conduct that is inevitable in the functioning of the 340B Program.

not a statutory mandate. Thus, manufacturers may not refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies.

II. Conclusion and Limitations

For these reasons, the Office of the General Counsel concludes that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients.[9]

This Advisory Opinion may be supplemented or modified by the Office of the General Counsel. It is intended to minimize the need for individual advisory opinions. This Advisory Opinion sets forth the current views of the Office of the General Counsel.[10] It is not a final agency action or a final order, and it does not have the force or effect of law.

Robert Charrow

Robert P. Charrow
General Counsel
December 30, 2020

[9] This Advisory Opinion is limited to interpretation of the 340B statutory requirements in general and does not opine on the legality of any specific contract-pharmacy model, under either the 340B statute or other laws that may apply (such as the anti-kickback statute, 42 U.S.C. § 1320a-7b).

[10] *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647–48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 ("The head of an executive department . . . may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]"); *Statement of Organization, Functions, and Delegations of Authority*, 85 Fed. Reg. 54,581, 54,583 (Sept. 2, 2020).

EXHIBIT H

Exhibit K

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201

September 21, 2020

Anat Hakim
Senior Vice President and General Counsel
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

Dear Ms. Hakim:

I am responding to your September 8, 2020 letter to the Deputy Secretary and me. In that letter, you requested a pre-enforcement advisory opinion ("AO") as to whether Lilly's new unilateral policy involving the 340B program would subject Lilly to sanctions. Under that policy, Lilly will cease extending 340B pricing to pharmacies under contract with covered entities, unless the covered entity lacks an in-house pharmacy.[1] In such a case, Lilly will extend 340B pricing to only one designated contract pharmacy. As we understand it, Lilly has already implemented that policy for Cialis and has since extended the same policy for its other covered outpatient drugs.

As we have indicated in earlier correspondence, although the Health Resources and Services Administration ("HRSA") has significant initial concerns with Lilly's new policy, it continues to review that policy and has yet to make a final determination as to any potential action. Correspondingly, Lilly cannot and should not view the absence of any questions from the government as somehow endorsing Lilly's policy especially when this Department is leading the government's response to the COVID-19 pandemic.

In the interim, we have four concerns with your letters that do not relate to the legal propriety of your unilateral price increases.

First, Lilly sought to unilaterally impose an artificial deadline on HRSA's decision-making when it asserted in its May 18, 2020, letter to HRSA that unless it heard from HRSA to the contrary by June 30, 2020, it would assume that HRSA had no objections to its price restructuring for Cialis and would implement the same on July 1. Lilly imposed a similar set of deadlines for the rest of its drugs, indicating in its August 19, 2020 letter to HRSA that unless Lilly heard to the contrary by August 31, 2020, it would begin charging higher prices to pharmacies under contract with covered entities serving the disadvantaged on September 1. Lilly cannot and should not seek to impose such deadlines on the government's deliberations—especially when HRSA is playing a pivotal role in responding to an unprecedented pandemic. Nor is Lilly entitled to know the substance of those ongoing deliberations.

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[1] In addition to the September 8 letter from you, Lilly has submitted four other letters with respect to its proposal to scrap 340B pricing to contract pharmacies—dated August 27, 2020, August 19, 2020, July 17, 2020, and May 18, 2020.

Second, Lilly's decision to interpret HRSA's responses as tantamount to definitive agency agreement with Lilly's position is incorrect. As noted above, HRSA is still evaluating how to proceed.

Third, Lilly's designation of its letters of September 8 and May 18 as exempt from disclosure under FOIA Exemptions 4, 6, and 7 and containing trade secrets under 18 U.S.C. § 1905 is fundamentally in error. Exemption 4 covers trade secrets and commercial confidential information. Lilly's legal position is neither. Moreover, we could find nothing in any of your letters that qualifies as either a trade secret or commercial confidential information. Exemption 6 relates to "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." We could find nothing in any of the Lilly letters that would qualify for this exemption. Exemption 7 relates to law-enforcement records. It is unclear why Lilly believes that Exemption 7 applies.

Fourth, we believe that the timing of your pricing changes is, at the very least, insensitive to the recent state of the economy. Although the economy is rebounding at a record rate, the unemployment and under-employment rates are still temporarily higher than at the beginning of the year due to COVID-19. Many Americans and many small businesses have had difficulty making ends meet. Lilly, on the other hand, seems to be enjoying an outstanding year. The price of Lilly's stock has increased by more than 11 percent since January 1, 2020, reflecting, among other things, the fact that your company's comprehensive income jumped from $1.414 billion during the second quarter of 2019 to $1.615 billion for the second quarter of 2020, an increase of more than 14 percent.

In contrast, during this same period, most health care providers, many of which are covered entities under section 340B, were struggling financially and requiring federal assistance from the Provider Relief Fund established by the CARES Act. Many continue to struggle and depend on emergency taxpayer assistance. It is against this backdrop that you are effectively increasing the prices of 10 mg and 20 mg Cialis by more than 500,000 percent and have done the same for other drugs in your portfolio.

In your letter, you noted that at least one covered entity has been the subject of a *qui tam* False Claims Act suit arising, in part, out of the 340B program. *See* Letter to the Deputy Secretary from Ms. Hakim (Lilly) at 2 n.6 (July 17, 2020); Letter to Rear Admiral Pedley from Mr. Asay (Lilly) at 11 n.36 (May 18, 2020). Please bear in mind that a similar suit against Lilly is a potential consequence in the event that Lilly knowingly violates a material condition of the program that results in over-charges to grantees and contractors.

Sincerely yours,

Robert P. Charrow
General Counsel

EXHIBIT I

Exhibit L

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857
Office of Pharmacy Affairs

December 9, 2020

Ms. Maureen Testoni
President and Chief Executive Officer
340B Health
1101 15th Street, NW, Suite 910
Washington, DC 20005

Dear Ms. Testoni:

Secretary Azar asked me to thank you for your letter regarding recent actions by several drug manufacturers impacting covered entities that participate in the 340B Drug Pricing Program (340B Program).

Your letter raises concerns about specific actions that limit access to 340B drugs. For example, Eli Lilly USA (Lilly) is no longer providing 340B discounts on several of its drug products to covered entities through contract pharmacy arrangements. Several other manufacturers have also announced plans not to sell 340B drugs to contract pharmacies, while others are limiting sales by requiring specific data requirements or selling drug products only after a covered entity has demonstrated 340B compliance.

The Health Resources and Services Administration (HRSA) is continuing to review the various proposals and whether these actions by manufacturers violate the 340B statute and whether sanctions may apply. Under section 340B(a)(1) of the Public Health Service Act (PHSA), a manufacturer participating in the 340B Program must offer its covered outpatient drugs for purchase at or below the 340B ceiling price. Those sanctions could include, but are not limited to, civil monetary penalties pursuant to section 340B (d)(1)(B)(vi) of the PHSA. In a letter to Lilly posted on the 340B website, the U.S. Department of Health and Human Services reiterates its concern with actions such as those Lilly is taking.[1]

The 340B statute does not specify the mode by which 340B drugs may be dispensed. HRSA believes contract pharmacies serve a vital function in covered entities' ability to serve underserved and vulnerable populations, particularly as many covered entities do not operate in-house pharmacies.

[1] See: https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf

HRSA believes that manufacturers that refuse to honor contract pharmacy orders could limit access to 340B-discounted drugs for many underserved and vulnerable populations who may be located in geographically isolated areas and rely on contract pharmacies as a critical point of access for obtaining their prescriptions. To this end, HRSA continues to strongly encourage all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy arrangements.

Some covered entities have reached out to HRSA expressing concern that they are unable to receive the 340B ceiling price on certain drug products due to these recent actions. HRSA is working closely with each impacted covered entity and is actively investigating the matter in order to make a final determination as to any potential action.

Sincerely,

Krista M. Pedley

Krista M. Pedley, PharmD, MS
RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs
Health Resources and Services Administration

EXHIBIT J

novo nordisk®

Notice Regarding Limitation on Hospital Contract Pharmacy Distribution

December 1, 2020

Beginning on January 1, 2021, Novo Nordisk Inc. (labeler codes 00169 and 71090) and Novo Nordisk Pharma, Inc. (labeler code 73070)) (Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. are collectively referred to herein as "Novo Nordisk") will no longer facilitate "bill-to/ship-to" distribution of 340B product to a contract pharmacy of any of the six "hospital" covered entity types.

If a "hospital" covered entity does not have an in-house pharmacy capable of dispensing product to outpatients, that covered entity may designate one contract pharmacy location to which product purchased by that covered entity may be shipped.

A hospital covered entity that does not maintain an on-site pharmacy at either a parent or child location may contact Novo Nordisk at 340BInfo@novonordisk.com to designate a single contract pharmacy location to accept bill-to/ship-to orders.

Novo Nordisk's new policy will not deny access to 340B-priced covered outpatient drugs to any "hospital" covered entity. Each may purchase as much Novo Nordisk product at the discounted 340B price that it wishes. At no time will Novo Nordisk fail to offer 340B prices to each and every 340B covered entity. It is merely the Novo Nordisk-facilitated shipment of that product to contract pharmacies (which are not themselves covered entities) that will be curtailed as of January 1, 2021.

None of the "grantee" covered entity types are impacted by this change in policy. Novo Nordisk will continue to facilitate contract pharmacy "bill-to/ship-to" arrangements for these covered entities. All "grantees," including Community Health Centers, Ryan White HIV Clinics, Hemophilia Treatment Centers, Indian Health Centers, and all other grantee covered entity types, may continue to place orders for Novo Nordisk product and have them shipped to their registered contract pharmacies, without limitation.

Questions about this policy change should be directed to 340BInfo@novonordisk.com .

* * *

Novo Nordisk Inc.
PCOR

800 Scudders Mill Road
Plainsboro, NJ 08536
USA

Telephone:
+1 609-987-5800

E-mail:
340BInfo@novonordisk.com
Internet:
www.novonordisk-us.com

EXHIBIT K

To Whom It May Concern:

I am writing to inform you that Sanofi is implementing a new 3408 program integrity initiative to address duplicate discounts. Sanofi supports the 3408 Program's core objective of increasing access to outpatient drugs among uninsured and vulnerable patients and is committed to maintaining and strengthening its mission. However, we are concerned about the rate of duplicate discounting on Medicaid prescriptions filled with 3408-purchased drugs. Similarly, manufacturers pay ineligible rebates on Medicare Part D and commercial utilization due to the lack of transparency in the 3408 program.

To resolve these issues, Sanofi will require 3408 covered entities to submit claims data for 3408 prescriptions of Sanofi products filled through its contract pharmacies. Sanofi will use this data to match against rebate claims it receives to ensure it isn't paying ineligible discounts. This initiative is enabled through 3408 E_S ™, a Second Sight Solutions technology. Sanofi is requiring 3408 covered entities to register at www.340BES.P..co.m by October 1, 2020.

Sanofi has maintained a strong commitment to the 3408 program since its inception. We also recognize that for the 3408 program to continue in its mission, serious program integrity and transparency challenges must be addressed. That is why we are adopting the 3408 ESP™ platform and we look forward to working with 3408 covered entities to further strengthen the 3408 program.

Best regards,

Gerald Gleeson
VP & Head, Sanofi US Market Access Shared Services

NEXT STEPS AND FREQUENTLY ASKED QUESTIONS

To get started with Second Sight Solutions' 3408 ESP™ platform, follow these three simple steps:

1. Go to www.340.B.ESP..c.om to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes -15 minutes.
2. Once your account is activated, you will be able to securely upload data to 3408 ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.
3. Login to 3408 ESP and submit your 3408 contract pharmacy claims data on a bi-weekly basis. Once your account is set up, the claims upload process takes – 5 minutes.

In addition to the frequently asked questions below, you can visit \iiN\f.V\!.•3.4.0.BESP•c.om/EAQ.s. to learn more about 3408 ESP™. For further help with the registration, account setup, and data submission process please call Second Sight Solutions at 888-398-5520. To learn more about how Sanofi is working to improve program integrity through 3408 ESP™, please contact Sanofi directly at Sano.fi3.4D.B.Op_em.tions@s.anoii..c_om.

Q: How will Sanofi use the 3408 claims data that we provide through 3408 ESP™?

A: Data uploaded by 3408 covered entities will be used to identify and resolve duplicate Medicaid and commercial rebates.

Q: How does 3408 ESP™ protect the privacy of my patients?

A: Data uploaded to 340B ESP™ is de-identified and meets the definition of a De-identified Data Set under HIPAA. This means no actual protected health information (PHI) is collected and the data cannot be combined with other data sets to reveal the identity of a patient. Additional security controls are embedded throughout the platform.

Q: Is Sanofi requesting data for all Sanofi products?

A: No. Sanofi is only requesting data for Sanofi drugs commonly dispensed through retail, specialty and outpatient pharmacies registered on the HRSA database as a contract pharmacy. Physician-administered drugs are not part of this program. 340B ESP™ automatically limits the data in your upload file to the applicable NDCs.

Q: What happens if my organization does not provide 3408 contract pharmacy claims data?

A: Sanofi is requiring 340B covered entities to register with 340B ESP™ and begin providing 340B claims data by October 1, 2020. 340B covered entities that elect not to provide 340B claims data will no longer be eligible to place Bill To / Ship To replenishment orders for Sanofi products dispensed through a contract pharmacy. All 340B covered entities will continue to be able to purchase Sanofi products at the 340B price when shipped to an address registered on the 3408 covered el'"!tity database as a parent or child site.

Q: Is Sanofi requesting data for pharmacies that are registered with HRSA as a covered entity?

A: No. Sanofi is only requesting data for 340B claims that originates from contract pharmacies. Covered entities do not need to provide 340B claims for prescriptions filled in their own outpatient pharmacies.

Q: What benefit does the 3408 covered entity realize by using 3408 ESP™?

A: By providing 340B claims data that originate from contract pharmacies, you will enable Sanofi to definitively identify duplicate Medicaid rebates. Covered entities will then be informed which pharmacies are dispensing 340B purchased drugs to Medicaid patients. This information can be used to further strengthen the audit processes and compliance controls of the covered entity.

Q: Does HRSA and/or Apexus support this initiative?

A: HRSA encourages 340B covered entities to work with pharmaceutical manufacturers in good faith to resolve issues of non-compliance in the 340B program. Although neither HRSA nor Apexus has commented publicly on this specific initiative, Sanofi believes 340B ESP™ provides a simple platform for Sanofi and 340B covered entities to engage collaboratively and in good faith to address duplicate discounts.

Q: How often will I need to upload 3408 contract pharmacy claims data to 3408 ESP™?

A: The 340B ESP™ platform requires claims uploads every two weeks. The actual upload process takes ~5 minutes and should not place significant burden on 340B covered entity operations. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform.

Q: What technology requirements exist to successfully upload data to 3408 ESP™?

A: 340B ESP™ is compatible with most internet browsers including Microsoft Edge, Google Chrome, Safari, FireFox and others. However, we strongly recommend using Google Chrome for the best user experience. Users will need an internet connection and access to a supported browser to successfully upload data.

EXHIBIT L

Published on *Novartis United States of America* (https://www.novartis.us)

New policy related to the 340B program [1]

We firmly support the intent of the 340B program to serve vulnerable patients. However, the exponential growth of vast networks of contract pharmacies – which have no basis in law – has undermined the integrity of the program.

We have listened to stakeholders, and, after careful consideration, we are taking a focused approach based on common-sense criteria that will help ensure that the program benefits patients of covered entities, as intended. Our policy will continue to honor contract pharmacy arrangements so long as they are located within a 40-mile radius of the covered entity hospital, which is consistent with federal policy regarding hospitals and off-site affiliates.

Notably, our policy does not apply to federal grantee covered entities such as Ryan White clinics and community health centers, and patient access to medicines will not be compromised.

340B program reform is needed, and we look forward to continuing to work with Congress, the Department of Health and Human Services, and other stakeholders to ensure that the program operates within its intended framework and thereby address the long-standing concerns that threaten the sustainability of the program.

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Source URL: https://www.novartis.us/news/statements/new-policy-related-340b-program

Links
[1] https://www.novartis.us/news/statements/new-policy-related-340b-program

EXHIBIT M

United Therapeutics
CORPORATION
Medicines for Life®

P.O. Box 14186
55 T.W. Alexander Drive
Research Triangle Park, NC 27709
tel 919.485.8350
fax 919.485.8352

To: 340B Covered Entity

From: Kevin Gray, Senior Vice President, Strategic Operations, United Therapeutics Corporation

Date: November 18, 2020

Subject: United Therapeutics Corporation 340B Contract Pharmacy Policy Effective November 20, 2020

Dear 340B Covered Entity:

We are writing to inform you of United Therapeutics Corporation's new 340B contract pharmacy policy. The policy will be implemented in two steps.

Orders placed on or after November 20, 2020:

- United Therapeutics Corporation will accept 340B contract pharmacy orders placed on or after November 20, 2020 only if the contract pharmacy was utilized by the covered entity for a valid 340B purchase of a United Therapeutics Corporation covered outpatient drug during the first three full quarters of the 2020 calendar year (i.e., January 1 through September 30, 2020).
- United Therapeutics Corporation will deny any 340B contract pharmacy orders where the contract pharmacy does not meet this requirement.
- To identify your contract pharmacies that are eligible under this policy, please visit UTAssist.com, select "Our Services" followed by "Product Distribution"
- If a covered entity does not have its own on-site pharmacy, United Therapeutics Corporation will provide the covered entity the opportunity to designate a single contract pharmacy for which United Therapeutics Corporation will accept 340B orders. To apply for this exception, please contact United Therapeutics Corporation at 340b@unither.com.

Orders placed on or after May 13, 2021:

- United Therapeutics Corporation will accept 340B contract pharmacy orders placed on or after May 13, 2021 only if the covered entity also has agreed to provide to United Therapeutics Corporation, and is providing on an ongoing basis, claims data associated with all 340B contract pharmacy orders of United Therapeutics Corporation's covered outpatient drugs placed after May 13, 2021 via a platform hosted by a third party with appropriate security and patient privacy safeguards.
- We will provide additional information to you with respect to the platform and this process in advance of May 13, 2021.

This policy will apply to all of United Therapeutics Corporation's covered outpatient drugs, except for ADCIRCA (tadalafil). United Therapeutics Corporation may revise this policy at its sole discretion at any time and without prior notice.

Please be advised that we have notified the Office of Pharmacy Affairs, Health Resources and Services Administration, of this policy.

For questions regarding this policy, please contact United Therapeutics Corporation at 340b@unither.com.

EXHIBIT N

THE 340B COALITION

July 16, 2020

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Recent Actions by Pharmaceutical Manufacturers Eli Lilly and Merck Impacting 340B Covered Entities

Dear Secretary Azar:

On behalf of the thousands of safety-net providers enrolled in the 340B federal drug discount program, the 340B Coalition wants to bring to your attention the actions of two global pharmaceutical companies that threaten to dramatically reduce the 340B benefit that safety-net hospitals, health centers, and clinics use to serve our nation's most vulnerable citizens. We ask that the Department of Health and Human Services (HHS) use its legal authority to halt these actions and protect these vital institutions and their patients.

Background

Eli Lilly recently announced in a notice published on the Health Resources and Services Administration's Office of Pharmacy Affairs website that, effective July 1, 2020, the company will no longer provide 340B pricing on three formulations of the drug Cialis when the 340B covered entity that purchased it elects to have it shipped to a 340B contract pharmacy.[1] Lilly has left the door open to taking similar action with other drugs. If this is allowed to stand, there would be nothing preventing Lilly from extending this policy to hundreds of very expensive drugs that qualify for 340B pricing, including critical drugs like Humalog. We believe this refusal to sell a drug at a 340B price based on where the covered entity elects to have its 340B drugs shipped violates the 340B statute's requirement that manufacturers must offer 340B prices to eligible covered entities.

By letter dated June 29, 2020, Merck asked 340B covered entities to submit contract pharmacy claims data for "commonly dispensed" Merck drugs to allow the company to prevent duplicate discounts related to contract pharmacies[2] and indicated that, without "significant cooperation" from covered entities, Merck "may take further action to address 340B Program integrity." This

[1] Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs, https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf.

[2] Merck expressed interest in preventing duplicate discounts under Medicaid, Medicare Part D, and commercial insurance plans. Federal law prohibits Medicaid duplicate discounts but does not address duplicate discounts under Medicare Part D or commercial plans. Federal law does not confer compliance obligations on covered entities related to non-Medicaid claims.

request goes well beyond inquiries that manufacturers often engage in to address compliance concerns. Threats of "further action" absent cooperation from covered entities with such an overly broad request is not supported under the 340B statute.

In the midst of a global pandemic, with drug prices already much too high and rising, these actions cannot be allowed to stand. It is in the public interest that the Administration act swiftly and firmly to stop these actions.

A Clear Violation of Statute

Congress created the 340B drug pricing program to allow safety-net providers "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[3] Covered entities use the savings created by 340B drug price discounts to support care for patients who are uninsured and underinsured without costing the American taxpayers a single dollar, as the savings come from manufacturer discounts.

340B providers are a vital part of our nation's health care safety net, as shown by their key role in our response to the COVID-19 pandemic, and their participation in 340B is central to their ability to achieve their mission. For example:

- Federally Qualified Health Centers -- whose authorizing statute explicitly requires them to provide required services such as pharmaceuticals by contractual or collaborative arrangements, if not directly[4] -- use the savings from the 340B program to underwrite the costs of providing free or heavily discounted medications to low-income uninsured and underinsured patients. These savings also support a range of other services, which vary based on the needs of each health center's community. Common examples include substance use disorder services, clinical pharmacy services, dental services, and programs to make pharmaceuticals accessible to patients who are homebound or who live in remote areas.
- Ryan White grantees use 340B savings to provide specialized and primary medical services, dental care, and other services to people living with HIV/AIDS.
- AIDS Drug Assistance Programs are fully dependent on 340B contract pharmacies for their direct purchase mechanisms and uninsured clients.
- Comprehensive hemophilia treatment centers (HTCs) use 340B program savings to maintain and expand clinical services for all bleeding disorders patients seen at their centers, including such non-reimbursable services as coordination of care, social work services, and physical therapy assessments as well as rural outreach clinics. Patients and their families rely on HTCs, which depend on 340B savings, for access to specialized, consistent, and high-quality treatment and education. With HTCs and their

[3] H.R. Rep. 102-384(II) at 12 (1992).
[4] 42 U.S.C.§ 254b(a)(1).

comprehensive care model enabled by 340B savings, patients have longer, healthier, and more productive lives.
- 340B hospitals provide 60 percent of all uncompensated care in the U.S. and 75 percent of all Medicaid hospital care.

The 340B statute requires manufacturers wishing to participate in Medicaid and Medicare Part B to enter into agreements with HHS that "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[5] There is no provision under the statute that allows Lilly to deny 340B pricing to a covered entity, or to require that a drug purchased by a covered entity be shipped only to locations that the manufacturer has approved. Therefore, Lilly's pharmacy policy is a clear violation of the law, and HHS is compelled to take action to stop it from being carried out.

We are concerned that Merck's wide-ranging request for all contract pharmacy claims data, to address so-called "duplicate discounts" under Medicaid, Medicare Part D, and commercial plans could be extremely burdensome for covered entities to meet. We also are concerned that the data sought by Merck to prevent Medicare Part D and commercial "duplicate discounts," neither of which is prohibited under the 340B statute, will only be used to benefit the company's financial bottom line, not 340B compliance. The 340B statute does not permit pharmaceutical manufacturers to set up barriers to 340B pricing. Under federal rules, if Merck has compliance concerns regarding a particular covered entity, the company can make a good-faith inquiry targeted to that entity.[6] If the inquiry does not resolve the company's concerns, a manufacturer can request to conduct an audit of the entity.[7] We ask HHS to prohibit Merck from establishing barriers to 340B by threatening to impose "substantially more burdensome" consequences if covered entities do not voluntarily participate in the company's unnecessary and burdensome program.

A Dangerous Precedent

We are concerned that the actions of these global manufacturers, if allowed to stand, will set a dangerous and negative precedent for the 340B program and the providers and patients it serves. These policies will hurt patients with low incomes and those living in rural communities who rely on 340B covered entities for their care. The Coalition appreciates the work that President Trump and you have done to halt the rise in prescription drug prices. Taking action today to halt these ill-conceived policies will be an important part of those efforts.

[5] 42 U.S.C. § 256b(a)(1).
[6] Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65406 (Dec. 12, 1996).
[7] 42 U.S.C. § 256b(a)(5)(C).

* * *

We appreciate your consideration of our request. If you have any questions, please feel free to reach out to any of the listed 340B Coalition representatives.

Sincerely,

The 340B Coalition

cc:
Tomas J. Engels, Administrator, Health Resources and Services Administration
Rear Admiral Krista M. Pedley, Director, Office of Pharmacy Affairs, Health Resources and Services Administration

340B Coalition Contacts

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340B Health
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EXHIBIT O

American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

July 30, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

On behalf of the American Hospital Association's (AHA) nearly 2,000 340B member hospitals, we are writing to express concern regarding recent action taken by three major drug manufacturers – Eli Lilly and Co., Merck and Sanofi – to limit the distribution of certain 340B drugs to our hospital members. Eli Lilly has filed its notice to limit the distribution of certain 340B drugs with the Office of Pharmacy Affairs within the Health Resources and Services Administration (HRSA). Merck and Sanofi have directly communicated with our 340B hospital members requesting detailed information about any 340B drugs distributed through the hospital's contract pharmacy arrangements. The Merck and Sanofi communications explain the purpose of the request is to investigate possible duplicate discounts provided to state Medicaid programs.

The 340B statute is clear that manufacturers wishing to participate in the Medicaid program must enter into agreements with the Department of Health and Human Services (HHS) that "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[1] Yet, Eli Lilly, Merck and Sanofi are moving forward with these actions in direct conflict with the statute and HRSA's 2010 guidance on contract pharmacy arrangements. The guidance clearly notes that: "Under section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the

[1] 42 U.S.C. 256b(a)(1)

manufacturer to sell the drug at a price not to exceed the statutory 340B discount price."[2] The HRSA guidance also makes it clear that the 340B covered entity is responsible for ensuring that the entity meets all requirements of the 340B program, including efforts to ensure against duplicate discounts and diversion. Eli Lilly has issued FAQs to justify its action to deny the distribution of certain 340B drugs through a hospital's contract pharmacy by stating that contract pharmacy arrangements are not statutory.

As noted in the guidance, HRSA established and expanded to use of contract pharmacy to improve access to 340B drugs for vulnerable populations served by the 340B program. 340B hospital and community health clinics are all obligated to meet the statutory and regulatory requirements of the 340B program. Neither the 340B statute nor the HRSA guidance would allow Eli Lilly to deny 340B pricing to a covered entity, or to require that a drug purchased by a covered entity be shipped only to locations that the manufacturer has approved. Eli Lilly, Merck and Sanofi are picking and choosing those requirements with which they will adhere. They are publicly flaunting the 340B statute and HRSA 340B programmatic guidance and taking matters into their own hands to suit their best interests.

The AHA urges HRSA to address these abuses by Merck, Eli Lilly and Sanofi and request they cease this activity and work to ensure that 340B drugs are available and accessible to communities and vulnerable populations. 340B hospitals continue to struggle to meet the demands of the COVID-19 public health emergency and it is outrageous that in the middle of a pandemic, hospitals are facing added challenges to the drug supply chain brought on by the actions of these major drug manufacturers.

We look forward to continuing to work with you during this critical time to protect the health of our nation. Please contact me if you have questions, or feel free to have a member of your team contact Molly Collins, director of policy, at (202) 626-2326 or mcollins@aha.org or Aimee Kuhlman, senior associate director of federal relations, at (202) 626-2291 or akuhlmanl@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President

[2] https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf

EXHIBIT P

AMERICA'S ESSENTIAL HOSPITALS

August 28, 2020

Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Ref: Pharmaceutical Company Actions Undermining 340B Drug Pricing Program

Dear Secretary Azar,

America's Essential Hospitals appreciates the actions of the Trump administration to mitigate the COVID-19 pandemic. We are encouraged that the Department of Health and Human Services (HHS) has provided flexibility throughout the pandemic that has been critical to providers on the front lines responding to the pandemic in their communities. In particular, the Health Resources & Services Administration (HRSA) issued guidance during this public health emergency to enable 340B Drug Pricing Program providers to continue to stretch their scarce resources and offer access to their vulnerable populations. Unfortunately, recent actions from multiple drug manufacturers threaten to undermine the progress the administration has made on reducing provider burden and tackling rising drug prices. We urge HHS to intervene to prevent these drug manufacturer actions from restricting access to lifesaving drugs.

Our more than 300 member hospitals serve a disproportionate share of low-income patients; as such, almost all qualify to participate in the 340B program. Essential hospitals, at the center of the nation's safety net, face the COVID-19 pandemic with short supplies of available resources. Costs associated with COVID-19 continue to rise while revenues decrease. Savings from the 340B program are more critical than ever to ensure our member hospitals can reach more patients and continue to offer vital services, safeguarding access to affordable health care for vulnerable individuals. Recent actions by five of the largest drug manufacturers threaten to undermine the ability of 340B hospitals to access affordable, lifesaving drugs for their patients. These actions are contrary to the 340B statute, add unnecessary burden on hospitals that already are stretched thin during an unprecedented pandemic, and impede vulnerable populations' access to affordable drugs.

To date, Eli Lilly and AstraZeneca have sent letters informing covered entities that the companies will cease shipping 340B-priced drugs to the recipients' contract pharmacies. While Eli Lilly's current actions are limited to one drug, AstraZeneca's action spans the scope of all contract pharmacy drugs. Three other manufacturers have taken a different approach. Merck, Sanofi, and Novartis have imposed arbitrary and ill-timed reporting requirements on 340B hospitals, requesting data on all contract pharmacy claims on a biweekly basis. The requested claims include Medicaid, Medicare Part D, and commercial claims. These manufacturers have threatened to take punitive measures if covered entities refuse to comply with these frivolous

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inquiries, including ceasing to ship 340B drugs to their contract pharmacies. These actions are problematic for many reasons.

First, these actions are a clear violation of drug manufacturers' statutory obligation to provide 340B discounts to covered entities. Under statute, drug manufacturers must provide 340B discounts to covered entities if they opt to have their drugs covered by the Medicaid prescription drug rebate program. The 340B statute is unequivocal in its requirement that these manufacturers provide 340B drugs to covered entities "at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[1] HRSA realized the importance of contract pharmacies in allowing for these arrangements in its previous guidance, and the manufacturers' actions flout this guidance, as well.

Second, the steps taken by the manufacturers will severely restrict access to affordable, lifesaving drugs for the most vulnerable populations, which depend on these drugs for treatment of acute and chronic conditions. Hospitals in the 340B program use HRSA-approved contract pharmacy arrangements to ensure they can expand access as widely as possible so patients can fill their prescriptions where it is most convenient for them. This is particularly true in the case of health systems that do not have expansive in-house pharmacy networks or that have patients facing barriers to access making it impractical to come to the hospital to replenish their supplies of needed medications. These patients include individuals living in rural areas and those facing various social risk factors, such as lack of transportation. If the manufacturers follow through with their threats to not honor 340B pricing at contract pharmacies, patients who have come to rely on contract pharmacies in their neighborhoods would be left without their usual source of discounted prescription drugs. Instead, they would have to purchase these drugs either at higher prices or at other pharmacies less accessible to them.

Third, the manufacturer actions are not based in any sound policy rationale. The manufacturers requesting contract pharmacy claims data cite concerns about duplicate discounts. However, the statutory prohibition on duplicate discounts only applies to the Medicaid context. Covered entities, in conjunction with state Medicaid programs, already take thorough steps in accordance with guidance from HRSA and the Centers for Medicare & Medicaid Services to avoid duplicate discounts. This includes appending claims modifiers to Medicaid claims, using the Medicaid exclusion file, and other actions. There is no reason related to 340B program integrity for manufacturers to seek to avoid duplicate discounts in the Medicare or commercial contexts, as there is no such thing as a duplicate discount in those contexts.

Finally, the requests place undue administrative burden on hospitals that works against this administration's efforts to reduce provider burden. The onerous manufacturer requests will further burden hospitals that already comply with numerous governmental and private stakeholder data reporting requests. Producing the claims data that manufacturers request on a biweekly basis will require dedicated staff time, if not the hiring of new staff dedicated to these requests. Considering the burden associated with complying with these inquiries, a pandemic is not the time to impose new data collection requests on 340B hospitals. These hospitals are singularly focused on responding to and recovering from COVID-19 and directing their staff toward these efforts.

For these reasons, we urge the agency to intervene to prevent manufacturers from undermining the 340B program and violating their statutory obligations. By putting a stop to these unjustified

[1] Public Health Service Act, section 340B(a)(1).

and burdensome actions, HHS will lift an unnecessary burden from hospitals and ensure continued access to affordable drugs, a key priority of this administration.

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America's Essential Hospitals appreciates your consideration of this letter. If you have questions, please contact Senior Director of Policy Erin O'Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO

EXHIBIT Q

American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

September 8, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

On behalf of the American Hospital Association's (AHA) nearly 2,000 340B member hospitals, we are writing to again express concern with recent actions taken by several major drug manufacturers to limit the distribution of certain 340B drugs to our hospital members. While we understand that the Health Resources and Services Administration (HRSA) is further investigating these actions, we urge swift and decisive action to halt these pernicious tactics so as to prevent other manufacturers from following suit.

In our July letter, we alerted you to actions taken by Eli Lilly and Merck to undermine the 340B program. Since that time, several other drug manufacturers – Sanofi, Novartis and AstraZenca – adopted similar strategies to interfere with 340B discounts for drugs distributed through contract pharmacy arrangements and/or demanding of 340B hospitals superfluous claims data requirements. These actions undermine 340B hospitals' ability to serve vulnerable communities, particularly in rural areas, where contract pharmacies help provide access to more affordable health care services.

The 340B statute is clear that manufacturers participating in the Medicaid program must enter into agreements with the Department of Health and Human Services (HHS) that "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[1] There is no statutory provision that allows these manufacturers to deny 340B pricing to eligible hospitals for any drug. In addition, 340B programmatic guidance states unequivocally that, "[u]nder section 340B, if a covered

[1] 42 U.S.C. 256b(a)(1)

entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price."[2] HHS, based on this alone, should act to compel drug manufacturers to halt these abusive tactics.

HRSA, in its oversight of the 340B program, found that expanding the use of contract pharmacies to improve access to 340B drugs for vulnerable communities served by the 340B program was critical, particularly in rural areas. Nearly half of all eligible 340B hospitals are in rural settings that often lack adequate access to health care services. Contract pharmacies expand access to affordable health care services for everyone in these vulnerable communities and the financial relief provided to rural hospitals from the exorbitant prices they would otherwise pay help keep them operating.

The AHA has written to each of these drug manufacturers' leadership to request they discontinue these abusive tactics. The responses received thus far cite unsubstantiated concerns about duplicate discounts between the Medicaid and 340B programs. However, even if these concerns are valid, there is no legitimate basis for these companies to limit the distribution of prescription drugs to 340B hospitals or demand superfluous paperwork.

The drug companies are attempting to exploit for their financial benefit the current COVID-19 health care crisis. As you are aware, hospitals throughout the nation are under severe stress by the need to prepare for, and/or care for, COVID-19 patients, while coping with the financial damages inflicted by the virus. Therefore, we urge you to act immediately against any drug manufacturer employing these pernicious tactics to ensure that 340B drugs are available and accessible to vulnerable communities.

We look forward to continuing to work with you during this critical time to protect our nation's health. Please contact me if you have questions, or feel free to have a member of your team contact Molly Collins, AHA's director of policy, at (202) 626-2326 or mcollins@aha.org or Aimee Kuhlman, AHA's senior associate director of federal relations, at (202) 626-2291 or akuhlman@aha.org.

Sincerely,

/s/

Richard J. Pollack
President and Chief Executive Officer

[2] https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf (emphasis supplied)

EXHIBIT R

American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
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(202) 638-1100

October 16, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

On behalf of the American Hospital Association's (AHA) nearly 2,000 340B member hospitals, we are writing to follow up on our previous correspondence on the serious situation Eli Lilly, AstraZeneca and Sanofi are creating for the nation's most vulnerable communities by refusing to comply with the requirements of the 340B program to sell to contract pharmacies at the discounts required by section 340B of the Public Health Service Act.

Despite correspondence to the drug manufacturers from AHA, 340B Health and others affected by this conduct followed by a letter from the Department of Health and Human Services' (HHS) General Counsel to Eli Lilly expressing "significant" concerns, Eli Lilly, Astra Zeneca and Sanofi have yet to halt their conduct, which is plainly illegal. Therefore, we request that HHS immediately direct all three companies to cease charging hospitals and covered entities more than the 340B ceiling price for drugs being dispensed by a contract pharmacy and pursuant to 42 U.S.C. § 256b(d)(1)(B)(ii) to issue refunds for each overcharge instance. We also request that the matter be referred to the HHS Office of Inspector General for assessment of civil money penalties pursuant to 42 C.F.R. § 10.11 and 42 C.F.R. Part 1003.[1]

Eli Lilly signaled its intent to flaunt the law in May 2020, when the Health Resources and Services Administration (HRSA) posted a notice from Eli Lilly, which states that, effective July 1, 2020, the company will no longer provide 340B pricing on three formulations of its drug Cialis® when the 340B covered entity purchasing the drug elects

[1] HRSA's civil money penalty regulations recognize that the penalties are in addition to repayment for overcharging as required by 42 U.S.C. § 256b(d)(1)(B)(ii). 42 C.F.R. § 10.11(a).

to have it shipped to a 340B contract pharmacy. *See Limited Distribution Plan Notice for Cialis®* on HRSA's website. On Sept. 1, 2020, Lilly extended this policy to all of its drugs, effective Oct. 1, 2020, and AstraZeneca and Sanofi quickly followed suit implementing similar policies withdrawing 340B pricing for their drugs when the covered entity elects to have the purchased drug shipped to a contract pharmacy.

These manufacturers' failure to sell their drugs to covered entities for delivery to patients through contract pharmacies at the 340B ceiling price is contrary to section 340B of the Public Health Service Act, 21 U.S.C. § 256b. Under the terms of the statute and the Pharmaceutical Pricing Agreement (PPA) these manufacturers have entered with HRSA under the statute, the manufacturers must charge covered entities no more than the 340B ceiling price for any covered outpatient drug. Failure to do so violates the 340B statute and the PPA.

As we further explain below, the plain meaning of the 340B statute requires all manufacturers to sell their drugs to covered entities at the 340B ceiling price, regardless of whether the drug is furnished at the entity's pharmacy or at a pharmacy that has entered into a contract with the covered entity to furnish 340B drugs to the covered entity's patients. HRSA has issued guidance on contract pharmacies that provides the correct interpretation of the statute. The statute does bind HHS and HRSA, and even without the guidance the statute would prohibit the manufacturers' conduct.

Under the 340B program, private prescription drug companies, as a condition of having their outpatient drugs covered through Medicaid, are required to enter into a PPA with the HHS Secretary pursuant to which they must offer 340B providers outpatient drugs at or below the ceiling price. Nothing in the statute limits how covered entities are permitted to get those drugs to their patients if the covered entity is complying with the statutory requirements, including the prohibition on drug diversion and duplicate discounting.

In 1996, HRSA issued "final guidelines" which recalled that since the beginning of the program, HHS has recognized that covered entities are permitted to use contract pharmacies to dispense 340B drugs as long as they comply with the prohibition on drug diversion. 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996) ("As early as 1993, several covered entity groups ... came forward to assist the Department in developing a workable mechanism to use outside pharmacies...")

The 1996 guidelines formalized a mechanism that covered entities could use to contract with a pharmacy to provide services to the covered entity's patients. 61 Fed. Reg. 43549. Although those guidelines provided only for the use of a single contract pharmacy, the limitation was driven by HRSA's desire to provide a mechanism that it thought would eliminate the risk of potential drug diversion rather than with a determination that HRSA believed it was not permitted. *Id.* In fact, HRSA agreed with comments that "[a]s a matter of State law, entities possess[ed] the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients" and that "even in the absence of Federal guidelines, covered entities have the right to

contract with retail pharmacies for the purpose of dispensing 340B drugs." HRSA also agreed that "[b]y issuing the guidelines, [the Office of Drug Policy, a Division of HRSA, was] not seeking to create a new right but rather [was] simply recognizing an existing right that covered entities enjoy under State law." *Id*. Finally, HRSA stated that "[u]nder section 340B, we believe that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. *Id.* at 43555 (emphasis added).[2]

In 2001, HRSA stated that certain covered entities could use more than one contract pharmacy, 75 Fed. Reg at 10273. And in 2007, HRSA proposed guidelines formally recognizing this mechanism. 72 Fed. Reg. 1540 (Jan 12, 2007). When those guidelines were finalized in 2010 (75 Fed. Reg. 10272), HRSA again recognized that "[u]nder section 340B*, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price." Id.* (emphasis added). Until now, Lilly and all other manufacturers have followed HRSA's interpretation of the statute. The refusal to follow the law is harming vulnerable communities and health care providers that the HHS General Counsel noted are already "struggling financially."

We are asking for a meeting with you and your staff to discuss what steps HHS intends to take to address this situation. We believe we can work together with you to halt this illegal conduct.

Please contact me if you have questions, or feel free to have a member of your team contact Molly Collins, director of policy, at 202-626-2326 or mcollins@aha.org or Aimee Kuhlman, senior associate director of federal relations, at 202-626-2291 or akuhlmanl@aha.org.

Sincerely,

/s/

Richard J. Pollack
President and Chief Executive Officer

[2] In response to comments arguing that the statute does not permit the use of contract pharmacy arrangements, HRSA noted that "[t]he statute is silent as to permissible drug distribution programs and that "[t]here is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." According to HRSA, "[i]t is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified groups of 340B covered entities." *Id.* at 43549.

EXHIBIT S

Pink Sheet
Informa Pharma Intelligence

340B Dispute Resolution Process On Ice As Feuds Between Pharma, Providers, HHS Heat Up

22 Jan 2021 | **ANALYSIS**

by **Cathy Kelly** | Catherine.Kelly@informa.com

Executive Summary

Biden Administration's regulatory freeze suspends HHS action to appoint an administrative dispute resolution board for the 340B program. Good news for manufacturers?

HHS ON THE HOT SEAT OVER 340B LEGAL QUESTIONS

Former Health and Human Services Secretary Alex Azar's last minute attempt to appoint a board to oversee a new 340B Administrative Dispute Resolution process at the department has been at least temporarily thwarted by the Biden Administration's regulatory freeze. The Administration's 21 January withdrawal of a rule to appoint the board will delay action on at least two ADR petitions that were recently filed against manufacturers.

Under a final rule establishing the ADR process, which was released in December, a six-member ADR board appointed by the secretary would guide the deliberations of a three-member ADR panel tasked with resolving disputes between manufacturers and providers over 340B pricing and other issues. (Also see "340B Needs A Stronger Fix Than Dispute Resolution Rule, Provider Lawsuit Against HHS Argues" - Pink Sheet, 15 Dec, 2020.)

The rule became effective on 13 January and ADR petitions protesting recent manufacturers actions to restrict 340B discounts to contract pharmacies quickly followed. One was filed on behalf of a Northern California-based federally qualified health center called Open Door Community Health against AstraZeneca, and another was submitted on behalf of the National Association of Community Health Centers against AstraZeneca PLC, Eli Lilly and Company, and Sanofi US.

The petitions ask that manufacturers be ordered to reinstate 340B discounts to all contract pharmacies and restore discounts lost after the companies began to withhold them. (Also see "Pharma Pressure On 340B Contract Pharmacies Builds; How Will Biden's HHS Respond?" - Pink Sheet, 4 Dec, 2020.)

"The 340B statute unambiguously requires respondent to sell covered outpatient drugs to petitioner and places no limitation on the site of delivery," the Open Door petition against AstraZeneca asserts. "A 340B regulation expressly defines a manufacturer overcharge to include an order placed through an 'agent,' such as a contract pharmacy." The petition by the National Association of Community Health Centers makes similar statements, arguing: "The drug manufacturers cannot impose their own unilateral conditions or restrictions on this unequivocal statutory requirement."

Without the organizational structure to handle them, the petitions are in effect on hold. President Biden's chief of staff on 20 January requested that federal agencies and departments suspend or withdraw last minute regulatory action by the Trump Administration that had not yet gone into effect until the actions could be reviewed by the new Administration. (Also see "Biden Regulatory Freeze May Pause Sunset Rule, Medicare Rebate, Medicaid Line Extension Regs" - Pink Sheet, 20 Jan, 2021.)

Rules that had not yet been published in the Federal Register, like the appointment of the ADR board, would be withdrawn and then would need to be re-proposed. The board would include officials from the HHS Office of General Counsel, the Health Resources and Services Administration and the Centers for Medicare and Medicaid Services, according to the final rule establishing the ADR process.

Also on hold is a final rule requiring federally qualified health centers to pass through all 340B discounts on insulin and EpiPens to consumers. The rule was meant to implement one of President Trump's executive orders on drug pricing. Its effective date, which had been scheduled for 22 January, is pushed back to 22 March.

Delay May Benefit Drug Industry Lawsuits

The delay in the ADR process may allow progress on a series of pharma industry lawsuits related to the ADR rule. Most recently, the Pharmaceutical Research and Manufacturers of America filed a complaint against HHS in federal district court in Maryland 22 January arguing that the ADR rule:

1. Is "arbitrary and capricious" and violates the Administrative Procedures Act;
2. Requires manufacturers to satisfy overly burdensome evidence requirements before they can begin an audit of a 340B entity suspected of diversion or contributing to duplicate discounts; and
3. Improperly gave ADR panel decisions binding and precedential effect, without review by agency officials who are appointed and confirmed by the Senate.

The PhRMA suit followed separate 12 January lawsuits by AstraZeneca, Sanofi and Lilly seeking to overturn a recently-issued HHS advisory opinion that concludes manufacturers are obligated by law to provide 340B discounts to contract pharmacies. AstraZeneca's complaint was filed in federal district court in Delaware, Sanofi's complaint was filed in New Jersey, and Lilly's complaint was filed in Indiana. (Also see "340B Fight: Lilly 'Disagrees' With HHS Advisory Stating Discounts To Contract Pharmacies Are Required" - Pink Sheet, 7 Jan, 2021.)

The advisory opinion could lend strong support to the pending ADR petitions against manufacturers brought by 340B covered entities.

They also seek a declaration by the courts that they are not legally required to provide discounts to contract pharmacies without any conditions. The companies believe the advisory opinion would undercut any defense against an administrative dispute regarding discounts to contract pharmacies. "HRSA has made clear that it intends to use the ADR process to impose liability on manufacturers for failure to follow the advisory opinion's approach to contract pharmacies," AstraZeneca's complaint says.

"Although Section 340B vests HHS with limited authority to establish ADR procedures by which to resolve 'claims' ... the ADR final rule purports to arrogate authority to the ADR panel 'to resolve related issues' – including purely legal questions such as ... whether

a pharmacy is part of a 'covered entity.'

"Even if that were a proper exercise of authority, which it is not, the advisory opinion already conclusively announces HHS's legal position on the contract pharmacy issue," the company continues. "Accordingly, any attempt by a manufacturer to contest the advisory opinion on the contract pharmacy issue in proceedings before an ADR panel would be an exercise in futility."

Advisory Opinion Followed Provider Lawsuit Against HHS

HHS issued the advisory opinion on 30 December after 340B-eligible providers filed suit against the department on 11 December seeking definitive action against the manufacturer restrictions. The suit was filed by the American Hospital Association, the American Society of Health-System Pharmacists, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association and 340B Health, as well as three individual hospital plaintiffs.

Lilly was the first company to announce restrictions on 340B discounts to contract pharmacies last summer. Six other companies have since imposed similar restrictions on discounts provided to contract pharmacies based on the belief that the retailers are improperly profiting from the 340B program and are engaged in product diversion and contribute to manufacturers providing duplicate discounts to 340B entities and Medicaid, which is prohibited by law.

The manufacturers' moves are aimed at exposing practices that are at odds with the underlying goal of the 340B program, which is to support safety net providers in their care of the underserved. A lack of transparency into how providers are using the savings from deep discounts has complicated efforts to resolve such complaints. The multiple lawsuits that the Biden Administration will now have to deal with may begin to provide some clarity.